Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 January 2016 to 31 January 2016

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC [1] or Article 38 of Directive 2001/82/EC [2])

(2016/C 076/02)

— **Issuing, maintenance or modification of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
7.1.2016	Solamocta	See Annex I	See Annex I	See Annex I	8.1.2016
14.1.2016	Ambroxol or Bromhexine	See Annex II	See Annex II	See Annex II	15.1.2016
18.1.2016	Bimatoprost	Bimatoprost	Not applicable	Not applicable	19.1.2016

See Annex.

These Decisions are addressed to the Member States.

[1] OJ L 311, 28.11.01, p. 67.
[2] OJ L 311, 28.11.01, p. 1.

ANNEX I

List of the names, pharmaceutical form, strength of the veterinary medicinal product, animal species, route of administration, applicant in the Member States

Member State EU/ EEA	Applicant	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Belgium	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Czech Republic	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Denmark	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
France	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral

Member State EU/ EEA	Applicant	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Greece	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Hungary	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Ireland	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Italy	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Luxembourg	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral

Member State EU/ EEA	Applicant	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Poland	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Portugal	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Slovakia	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
Spain	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
The Netherlands	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral
United Kingdom	Eurovet Animal Health BV Handelsweg 25 NL-5531 AE Bladel The Netherlands	Solamocta 697 mg/g Powder for Use in Drinking Water for Chickens, Ducks and Turkeys	Amoxicillin trihydrate	800 mg/g	Powder for use in drinking water	Chickens (broilers, pullets, breeders), ducks (broilers, breeders), turkeys	Oral

ANNEX II

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the Member States

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Bromhexidine hydrochloride	Bisolvon Hustenlöser — Saft	4 mg/5 ml	oral liquid	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Bromhexidine hydrochloride	Bisolvon — Lösung	8 mg/4 ml	oral solution	oral use
Austria	ratiopharm Arzneimittel Vertriebs-GmbH Albert Schweitzergasse 3 Vienna 1140 Austria	Ambroxole hydrochloride	Ambrobene retard 75 mg — Kapseln	75 mg	prolonged-release capsule, hard	oral use
Austria	ratiopharm Arzneimittel Vertriebs-GmbH Albert Schweitzergasse 3 Vienna 1140 Austria	Ambroxole hydrochloride	Ambrobene 15 mg/5 ml — Saft	15 mg/5 ml	oral liquid	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Aponova-Pharma Handels GmbH Mitterweg 4 Hart 6265 Austria	Ambroxole hydrochloride	Ambroxol 'Aponova' 60 mg — Brausetabletten	60 mg	effervescent tablet	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucoangin Johannisbeere 20 mg — Lutschtabletten	20 mg	lozenge	oral use
Austria	ratiopharm Arzneimittel Vertriebs-GmbH Albert Schweitzergasse 3 Vienna 1140 Austria	Ambroxole hydrochloride	Ambrobene 30 mg — Tabletten	30 mg	tablet	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucoangin Zitrone 20 mg Lutschtabletten	20 mg	lozenge	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride, clenbuterol	Mucospas — Tabletten	30 mg, 0,02 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride, clenbuterol	Mucospas — Saft	7,5 mg/5 ml, 0,0001 g	oral liquid	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucosolvan 7,5 mg/1 ml — Lösung	7,5 mg/ml	oral solution	oral use
Austria	ratiopharm Arzneimittel Vertriebs-GmbH Albert Schweitzergasse 3 Vienna 1140 Austria	Ambroxole hydrochloride	Ambrobene 15 mg — Ampullen	15 mg	solution for injection	intravenous use, intramuscular use, subcutaneous use
Austria	Genericon Pharma GmbH Hafnerstrasse 211 Graz 8054 Austria	Ambroxole hydrochloride	Ambroxol Genericon 30 mg Tabletten	30 mg	tablet	oral use
Austria	Genericon Pharma GmbH Hafnerstrasse 211 Graz 8054 Austria	Ambroxole hydrochloride	Ambroxol Genericon Lösung	7,5 mg/ml	oral solution	oral use
Austria	Genericon Pharma GmbH Hafnerstrasse 211 Graz 8054 Austria	Ambroxole hydrochloride	Ambroxol Genericon Saft	15 mg/5 ml	oral liquid	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucosolvan 15 mg — Lutschpastillen	15 mg	lozenge	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucosan 15 mg — Ampullen	15 mg	solution for injection	intravenous use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucosolvan retard 75 mg — Kapseln	75 mg	prolonged-release capsule, hard	oral use
Austria	1A Pharma GmbH Stella-Klein-Löw-Weg 17 Vienna 1020 Austria	Ambroxole hydrochloride	Ambroxol 1A Pharma 7,5 mg/ml — Lösung	7,5 mg/ml	oral solution	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucoangin Mint 20 mg — Lutschtabletten	20 mg	lozenge	oral use
Austria	+pharma arzneimittel gmbh Hafnerstrasse 211 Graz 8054 Austria	Ambroxole hydrochloride	Ambroxol + pharma 60 mg lösliche Tabletten	60 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Genericon Pharma GmbH Hafnerstrasse 211 Graz 8054 Austria	Ambroxole hydrochloride	Ambroxol Genericon 60 mg lösliche Tabletten	60 mg	effervescent tablet	oral use
Austria	ratiopharm Arzneimittel Vertriebs-GmbH Albert Schweitzergasse 3 Vienna 1140 Austria	Ambroxole hydrochloride	Ambrobene 7,5 mg/ml — Lösung	7,5 mg/ml	oral solution	oral use
Austria	Hexal Pharma GmbH Stella-Klein-Löw-Weg 17 Vienna 1020 Austria	Ambroxole hydrochloride	Ambrohexal 30 mg — lösbare Tabletten	30 mg	effervescent tablet	oral use
Austria	Hexal Pharma GmbH Stella-Klein-Löw-Weg 17 Vienna 1020 Austria	Ambroxole hydrochloride	Ambrohexal 7,5 mg/ml — Lösung	7,5 mg/ml	oral solution	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucoangin 17,86 mg/ml Spray zur Anwendung in der Mundhöhle	17,86 mg/ml	oromucosal spray	oral use
Austria	G.L. Pharma GmbH Schlossplatz 1 Lannach 8502 Austria	Ambroxole hydrochloride	Ambrolan 30 mg — Tabletten	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucosolvan 30 mg/5 ml — Saft	30 mg/ml	oral liquid	oral use
Austria	Boehringer Ingelheim RCV GmbH & Co KG Dr. Boehringergasse 5-11 Vienna 1121 Austria	Ambroxole hydrochloride	Mucosolvan 15 mg/5 ml — Saft für Kinder	15 mg/5 ml	oral liquid	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Ambroxine	2,5 mg/ml	oromucosal spray	inhalation use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Ambroxine	20 mg	pastille	oropharyngeal use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Ambroxine	20 mg	lozenge	oropharyngeal use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Bisolangin	20 mg	pastille	oromucosal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Mucoangin	2,5 mg/ml	oromucosal spray	oromucosal use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Mucoangin Cassis	20 mg	pastille	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Mucoangin Citron	20 mg	lozenge	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Mucoangin Menthe	20 mg	pastille	oropharyngeal use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Mucoangin Menthe	20 mg	lozenge	oropharyngeal use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Rexambro	20 mg	lozenge	oropharyngeal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Surbronc	30 mg/5 ml	syrup	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Surbronc	60 mg	tablet	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Ambroxol Hydrochloride	Surbronc	60 mg	granules for oral solution	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Bromhexine Hydrochloride	Bisolvon	2 %	nebuliser solution	inhalation use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Bromhexine Hydrochloride	Bisolvon	2 mg/ml	oral drops, solution	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Bromhexine Hydrochloride	Bisolvon	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Bromhexine Hydrochloride	Bisolvon	8 mg/5 ml	syrup	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Bromhexine Hydrochloride	Bisolvon Citrus	8 mg	tablet	oral use
Belgium	Boehringer Ingelheim S.C.S.-Comm. V. Avenue Ariane 16 1200 Brussels Belgium	Bromhexine Hydrochloride	Bisolvon Instant	8 mg	tablet	oral use
Belgium	E.G. S.A.-N.V. Heizel Esplanade b22 1020 Brussels Belgium	Bromhexine Hydrochloride	Bromhexine	8 mg	tablet	oral use
Belgium	D.J. Van Tintelen Beheer B.V. Stijntjesduinstraat 41 Noordwijk The Netherlands	Bromhexine Hydrochloride	Bronchi-Mereprine	8 mg	tablet	oral use
Belgium	Laboratoria Qualiphar N.V/S.A Rijksweg 9 2880 Bornem Belgium	Bromhexine Hydrochloride	Toularynx Bromhexine	5 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Sopharma AD 16, Iliensko shosse str. Sofia 1220 Bulgaria	Ambroxol hydrochloride	Ambixol	15 mg/5 ml	syrup	oral use
Bulgaria	Nobel Pharma OOD 24 Simeonovsko shose bulvd. 1700 Sofia Bulgaria	Ambroxol hydrochloride	Ambrex	15 mg/5 ml	syrup	oral use
Bulgaria	Nobel Pharma OOD 24 Simeonovsko shose bulvd. 1700 Sofia, Bulgaria	Ambroxol hydrochloride	Ambrex	30 mg/5 ml	syrup	oral use
Bulgaria	Tchaikapharma Highquality Medicines 1 G. M. Dimitrov Blvd Sofia, 1172 Bulgaria	Ambroxol hydrochloride	Ambrin	30 mg	effervescent tablet	oral use
Bulgaria	Hexal AG Industriestrasse 25, D-83607 Holzkirchen, Germany	Ambroxol hydrochloride	Ambro	3 mg/ml	oral solution	oral use
Bulgaria	Hexal AG Industriestrasse 25, D-83607 Holzkirchen, Germany	Ambroxol hydrochloride	Ambro	30 mg	tablet	oral use
Bulgaria	Aliud Pharma GmbH 19 Gottlieb-Daimler-Str. 89150 Laichingen, Germany	Ambroxol hydrochloride	Ambrolex R	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Adipharm EAD 130 Simeonovsko Shosse blvd 1700 Sofia Bulgaria	Ambroxol hydrochloride	Ambroxol Adipharm	15 mg/5 ml	syrup	oral use
Bulgaria	Berlin-Chemie AG Glienicker Weg 125 — 127 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	60 mg	effervescent tablet	oral use
Bulgaria	Berlin-Chemie AG Glienicker Weg 125 — 127 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	15 mg/5 ml	oral solution	oral use
Bulgaria	Berlin-Chemie AG Glienicker Weg 125 — 127 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed Cough Tablets	30 mg	tablet	oral use
Bulgaria	Berlin-Chemie AG Glienicker Weg 125 — 127 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed for children	15 mg/5 ml	oral solution	oral use
Bulgaria	Berlin-Chemie AG Glienicker Weg 125 — 127 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed forte	30 mg/5 ml	oral solution	oral use
Bulgaria	Berlin-Chemie AG Glienicker Weg 125 — 127 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed max	30 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Cyathus Exquirere Pharmaforschungs GmbH Rudolfsplatz 2/1/8 1010 Wienna Austria	Ambroxol hydrochloride	Gogolox	5 %	oral solution	oral use
Bulgaria	Aliud Pharma GmbH 19 Gottlieb-Daimler-Str. 89150 Laichingen, Germany	Ambroxol hydrochloride	Grippostad Ambro	30 mg	tablet	oral use
Bulgaria	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucoangin	20 mg	lozenge	oral use
Bulgaria	Actavis EAD 29 Atanas Dukov str. 1407 Sofia Bulgaria	Ambroxol hydrochloride	Mucolisin	30 mg/5 ml	syrup	oral use
Bulgaria	Zentiva, a.s. Einsteinova 24 851 01, Bratislava Slovak Republic	Ambroxol hydrochloride	Mucosin Zentiva	30 mg	tablet	oral use
Bulgaria	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	15 mg	pastille	oral use
Bulgaria	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	75 mg	prolonged-release capsule, hard	oral use
Bulgaria	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	30 mg/5 ml	syrup	oral use
Bulgaria	Divapharma GmbH Motzener Straße 41 12277 Berlin Germany	Ambroxol hydrochloride	Neo-bronchol	15 mg	lozenge	oral use
Bulgaria	KRKA, d.d. Smarjeska cesta 6 Novo mesto, 8501 Slovenia	Ambroxol hydrochloride	Solvolan	15 mg/5 ml	syrup	oral use
Bulgaria	KRKA, d.d. Smarjeska cesta 6 Novo mesto, 8501 Slovenia	Ambroxol hydrochloride	Solvolan	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Actavis EAD 29 Atanas Dukov str. 1407 Sofia Bulgaria	Bromhexine hydrochloride	Bromhexin Actavis	4 mg	coated tablet	oral use
Bulgaria	Actavis EAD 29 Atanas Dukov str. 1407 Sofia Bulgaria	Bromhexine hydrochloride	Bromhexin Actavis	8 mg	coated tablet	oral use
Bulgaria	Sopharma AD 16, Iliensko shosse str. Sofia, 1220 Bulgaria	Bromhexine hydrochloride	Bromhexine Sopharma	2 mg/ml	solution for injection	intramuscular use, intravenous use
Bulgaria	Sopharma AD 16, Iliensko shosse str. Sofia, 1220 Bulgaria	Bromhexine hydrochloride	Bromhexine Sopharma	8 mg	tablet	oral use
Croatia	Medis Adria d.o.o. Kolarova 7, Zagreb 10000 Croatia	ambroxolum	Ambrospray 10 mg/potisku spreja, oralna otopina	50 mg/ml	oral solution	oral use
Croatia	Boehringer Ingelheim Zagreb d.o.o. Radnička 40-5, Zagreb 10000 Croatia	ambroxolum	Mucosolvan 75 mg kapsule s produljenim oslobađanjem	75 mg	prolonged-release capsule	oral use
Croatia	Berlin-Chemie Menarini Hrvatska d.o.o. Horvatova 80a, Zagreb 10000 Croatia	ambroxolum	Flavamed 15 mg/5 ml oralna otopina	15 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Croatia	Berlin-Chemie Menarini Hrvatska d.o.o. Horvatova 80a, Zagreb 10000 Croatia	ambroxolum	Flavamed forte 30 mg/5 ml oralna otopina	30 mg/5 ml	oral solution	oral use
Croatia	Berlin-Chemie Menarini Hrvatska d.o.o. Horvatova 80a, Zagreb 10000 Croatia	ambroxolum	Flavamed 30 mg tablete	30 mg	tablet	oral use
Croatia	Berlin-Chemie Menarini Hrvatska d.o.o. Horvatova 80a, Zagreb 10000 Croatia	ambroxolum	Flavamed forte 60 mg šumeće tablete	60 mg	effervescent tablet	oral use
Croatia	Boehringer Ingelheim Zagreb d.o.o. Radnička 40-5, Zagreb 10000 Croatia	ambroxolum	Mucosolvan 30 mg tablete	30 mg	tablet	oral use
Croatia	Divapharma GmbH Motzener Str. 41, Berlin 12277 Germany	ambroxolum	neo-bronchol 15 mg pastile	15 mg	pastille	oral use
Croatia	Pliva Hrvatska d.o.o. Prilaz baruna Filipovića 25, Zagreb 10000 Croatia	bromhexinum	Bisolex 2 mg/ml otopina	2 mg/ml	oral drops, solution	oral use
Croatia	Pliva Hrvatska d.o.o. Prilaz baruna Filipovića 25, Zagreb 10000 Croatia	bromhexinum	Bisolex 4 mg/5 ml sirup	4 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Croatia	Pliva Hrvatska d.o.o. Prilaz baruna Filipovića 25, Zagreb 10000 Croatia	bromhexinum	Bisolex 8 mg tablete	8 mg	tablet	oral use
Croatia	Pliva Hrvatska d.o.o. Prilaz baruna Filipovića 25, Zagreb 10000 Croatia	bromhexinum	Bisolex F 16 mg tablete	16 mg	tablet	oral use
Croatia	Boehringer Ingelheim Zagreb d.o.o. Radnička 40-5, Zagreb 10000 Croatia	bromhexinum	Bisolvon 2 mg/ml otopina	2 mg/ml	solution for oral use	oral use
Croatia	Boehringer Ingelheim Zagreb d.o.o. Radnička 40-5, Zagreb 10000 Croatia	bromhexinum	Bisolvon 4 mg/5 ml sirup	4 mg/5 ml	syrup	oral use
Croatia	Boehringer Ingelheim Zagreb d.o.o. Radnička 40-5, Zagreb 10000 Croatia	bromhexinum	Bisolvon 8 mg tablete	8 mg	tablet	oral use
Cyprus	The Star Medicines Importers & Co Ltd 9A Loukis Akritas Street Lemesos 3601 Cyprus	ambroxol hydrochloride	Anavix	15 mg/5 ml	syrup	oral use
Cyprus	Varnavas Hadjipanayis Ltd Yiannou Kranidioti Avenue 226 Latsia/Lefkosia 2234 Cyprus	ambroxol hydrochloride	Fluibron	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Cyprus	CDL Pharmaceutical Products Ltd 12 Agiou Spiridonos Street Aradippou/Larnaca 7102 Cyprus	ambroxol hydrochloride	Hyvotex	30 mg/5 ml	syrup	oral use
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos Street P.O. BOX 51409 3505 Lemesos Cyprus	ambroxol hydrochloride	Medovent	30 mg	tablet	oral use
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos Street P.O. BOX 51409 3505 Lemesos Cyprus	ambroxol hydrochloride	Medovent elixir	15 mg/5 ml	syrup	oral use
Cyprus	Mundipharma Pharmaceuticals Ltd 13 Othellos Street Dhali Industrial Zone 1685 Lefkosia Cyprus	ambroxol hydrochloride	Mucobroxol	15 mg/5 ml	syrup	oral use
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Mucosolvan	30 mg/5 ml	syrup	oral use
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Mucosolvan oral Gum	15 mg	oral gum	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Mucosolvan	30 mg	tablet	oral use
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Mucosolvan	15 mg/5 ml	syrup	oral use
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Mucosolvan	75 mg	prolonged-release tablet	oral use
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Mucosolvan	7,5 mg/ml	solution for injection	intramuscular use, intravenous use
Cyprus	Boehringer Ingelheim Ellas AE Ellinikou 2 Street 16777 Athens Greece	ambroxol hydrochloride	Lysopadol	20 mg	lozenge	oral use
Cyprus	REMEDICA LTD Aharnon street P.O. Box 51706 3508 Lemesos Cyprus	bromhexine hydrochloride	Flecoxin Elixir	4 mg	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Cyprus	REMEDICA LTD Aharnon street P.O. Box 51706 3508 Lemesos Cyprus	bromhexine hydrochloride	Flecoxin	4 mg	tablet	oral use
Cyprus	REMEDICA LTD Aharnon street P.O. Box 51706 3508 Lemesos Cyprus	bromhexine hydrochloride	Flecoxin	8 mg	tablet	oral use
Czech Republic	WALMARK, a.s. Oldřichovice 44 739 61 Třinec Czech Republic	ambroxol hydrochloride	Ambex	60 mg	effervescent tablet	oral use
Czech Republic	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene	7,5 mg/ml	solution for injection	intravenous use, intramuscular use, subcutaneous use
Czech Republic	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 15 mg/5 ml	3 mg/ml	syrup	oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague 5 Czech Republic	ambroxol hydrochloride	Ambrobene 3 mg/ml	3 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 30 mg	30 mg	tablet	oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague 5 Czech Republic	ambroxol hydrochloride	Ambrobene 6 mg/ml	6 mg/ml	oral solution	oral use
Czech Republic	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 7,5 mg/ml	7,5 mg/ml	oral solution	oral use
Czech Republic	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 75 mg	75 mg	prolonged-release capsule, hard	oral use
Czech Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Prague 4 Czech Republic	ambroxol hydrochloride	Ambrosan 15 mg	15 mg	tablet	oral use
Czech Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Prague 4 Czech Republic	ambroxol hydrochloride	Ambrosan 15 mg/5 ml Sirup	3 mg/ml	syrup	oral use
Czech Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Prague 4 Czech Republic	ambroxol hydrochloride	Ambrosan 30 mg	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Prague 4 Czech Republic	ambroxol hydrochloride	Ambrosan 60 mg	60 mg	tablet	oral use
Czech Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Prague 4 Czech Republic	ambroxol hydrochloride	Ambrosan kapky	7,5 mg/ml	oral drops, solution	oral use
Czech Republic	CYATHUS Exquirere Pharmaforschungs GmbH Rudolfsplatz 2/8 1010 Wien Austria	ambroxol hydrochloride	Ambrospray 5 %	50 mg/ml	oromucosal spray	oromucosal use
Czech Republic	Aliud Pharma GmbH Gottlieb-Daimler-Strasse 19 89150 Laichingen Germany	ambroxol hydrochloride	Ambroxol Al 30	30 mg	tablet	oral use
Czech Republic	Aliud Pharma GmbH Gottlieb-Daimler-Strasse 19 89150 Laichingen Germany	ambroxol hydrochloride	Ambroxol Al 75 Retard	75 mg	prolonged-release capsule, hard	oral use
Czech Republic	Aliud Pharma GmbH Gottlieb-Daimler-Strasse 19 89150 Laichingen Germany	ambroxol hydrochloride	Ambroxol Al kapky	7,5 mg/ml	oral drops, solution	oral use
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Ambroxol Berlin-Chemie 30 mg/5 ml perorální roztok	6 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed 15 mg/5 ml perorální roztok	3 mg/ml	oral solution	oral use
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed effervescent tablet 60 mg	60 mg	effervescent tablet	oral use
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed Forte 30 mg/5 ml	6 mg/ml	oral solution	oral use
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed tablety	30 mg	tablet	oral use
Czech Republic	Egis Pharmaceuticals PLC Keresztúri út. 30-38 1106 Budapest Hungary	ambroxol hydrochloride	Halixol 30 mg	30 mg	tablet	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130 Dolni Měcholupy 102 37 Prague 10 Czech Republic	ambroxol hydrochloride	Mucosin s medem sir	3 mg/ml	syrup	oral use
Czech Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan	7,5 mg/ml	oral drops, solution /inhalation solution	oral use, inhalation use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan	30 mg	tablet	oral use
Czech Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan	15 mg	pastille	oromucosal use
Czech Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan Junior	3 mg/ml	syrup	oral use
Czech Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan Long Effect	75 mg	prolonged-release capsule, hard	oral use
Czech Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan pro dospělé	6 mg/ml	syrup	oral use
Czech Republic	Divapharma GmbH Motzener Str. 41 12277 Berlin Germany	ambroxol hydrochloride	Neo-Bronchol	15 mg	lozenge	oromucosal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	ambroxol hydrochloride	Solvolan	3 mg/ml	syrup	oral use
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	bromhexine hydrochloride	Bromhexin 12 BC	12 mg/ml	oral drops, solution	oral use
Czech Republic	Krewel Meuselbach GmbH Krewelstrasse 2 53783 Eitorf Germany	bromhexine hydrochloride	Bromhexin 12 KM-kapky	12 mg/ml	oral drops, solution	oral use
Czech Republic	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	bromhexine hydrochloride	Bromhexin 8 Berlin-Chemie	8 mg	coated tablet	oral use
Czech Republic	Krewel Meuselbach GmbH Krewelstrasse 2 53783 Eitorf Germany	bromhexine hydrochloride	Bromhexin 8 KM kapky	8 mg/ml	oral drops, solution	oral use
Czech Republic	Krewel Meuselbach GmbH Krewelstrasse 2 53783 Eitorf Germany	bromhexine hydrochloride	Bromhexin 8-sirup KM	0,8 mg/ml	syrup	oral use
Czech Republic	GALMED a.s. Těšínská 1349/296 716 00 Ostrava — Radvanice Czech Republic	bromhexine hydrochloride	Bromhexin Galmed 12	12 mg/ml	oral drops, solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Czech Republic	GALMED a.s. Těšínská 1349/296 716 00 Ostrava — Radvanice Czech Republic	bromhexine hydrochloride	Bromhexin Galmed 8	8 mg/ml	oral drops, solution	oral use
Czech Republic	Egis Pharmaceuticals PLC Keresztúri út. 30-38 1106 Budapest Hungary	bromhexine hydrochloride	Bromhexin-Egis	2 mg/ml	oral solution	oral use
Czech Republic	Egis Pharmaceuticals PLC Keresztúri út. 30-38 1106 Budapest Hungary	bromhexine hydrochloride	Paxirasol	2 mg/ml	solution for injection	intravenous use, intramuscular use, subcutaneous use
Denmark	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed	60 mg	effervescent tablet	oral use
Denmark	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed	6 mg/ml	oral solution	oral use
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucoangin	20 mg	compressed lozenge	oral use
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucoangin	2,5 mg/dose	oromucosal spray, solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucoangin Citron	20 mg	compressed lozenge	oral use
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucoangin Cassis	20 mg	compressed lozenge	oral use
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	bromhexine hydrochloride	Bisolvon	0,8 mg/ml	oral solution	oral use
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	bromhexine hydrochloride	Bisolvon	8 mg	tablet	oral use
Denmark	Boehringer Ingelheim Int. GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	bromhexine hydrochloride	Bisolvon	8 mg	soluble tablet	oral use
Denmark	Takeda Pharma A/S Dybendal Aile 10 2630 Taastrup Denmark	bromhexine hydrochloride	Bromhexin 'DAK'	0,8 mg/ml	oral solution	oral use
Denmark	Takeda Pharma A/S Dybendal Aile 10 2630 Taastrup Denmark	bromhexine hydrochloride	Bromhexin 'DAK'	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Estonia	AS Grindeks Krustpils 53 1057 Riga Latvia	Bromhexine	Bromhexine-Grindeks	0,8 mg/ml	syrup	oral use
Estonia	AS Grindeks Krustpils 53 1057 Riga Latvia	Bromhexine	Bromhexine-Grindeks	8 mg	tablet	oral use
Estonia	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Ambroxol	Ambrolan	30 mg	tablet	oral use
Estonia	Sandoz d.d. Verovskova 57 1000 Ljubljana Slovenia	Ambroxol	Ambroxol Sandoz 15 mg/5 ml	3 mg/ml	syrup	oral use
Estonia	Sandoz d.d. Verovskova 57 1000 Ljubljana Slovenia	Ambroxol	Ambroxol Sandoz 30 mg	30 mg	tablet	oral use
Estonia	PRO. MED. CS. PRAHA a.s Telcska 1 14000 Praha 4 Czech Republic	Ambroxol	Pro-Ambrosan	30 mg	tablet	oral use
Estonia	BOEHRINGER INGELHEIM INTERNATIONAL GmbH — Binger Strasse 173 Ingelheim/Rhein 55216 Germany	Ambroxol	Lasolvan	3 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Estonia	ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Ambroxol	Brontex Lahus	7,5 mg/ml	oral solution	oral use
Estonia	ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Ambroxol	Brontex Tabletid	30 mg	tablet	oral use
Estonia	ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Ambroxol	Brontex Siirup	3 mg/ml	syrup	oral use
Estonia	DIVAPHARMA GmbH Motzener Str. 41 12277 Berliin Germany	Ambroxol	Neo-Bronchol	15 mg	pastille	oral use
Estonia	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 12489 Berlin Germany	Ambroxol	Flavamed 30 Mg	30 mg	tablet	oral use
Estonia	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 12489 Berlin Germany	Ambroxol	Flavamed 60 mg	60 mg	effervescent tablet	oral use
Estonia	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 12489 Berlin Germany	Ambroxol	Flavamed Forte	6 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Estonia	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 12489 Berlin Germany	Ambroxol	Flavamed Vaarikas	3 mg/ml	oral solution	oral use
Finland	Berlin-Chemie AG Glienicker Weg 125 12489 BERLIN Germany	Ambroxol hydrochloride	FLAVAMED	30 mg	tablet	oral use
Finland	Berlin-Chemie AG Glienicker Weg 125 12489 BERLIN Germany	Ambroxol hydrochloride	FLAVAMED	60 mg	effervescent tablet	oral use
Finland	Berlin-Chemie AG Glienicker Weg 125 12489 BERLIN Germany	Ambroxol hydrochloride	FLAVAMED	6 mg/ml	oral solution	oral use
Finland	Berlin-Chemie AG Glienicker Weg 125 12489 BERLIN Germany	Ambroxol hydrochloride	FLAVAMED	3 mg/ml	oral solution	oral use
Finland	Boehringer Ingelheim International GmbH Binger Strasse 173 P.O. BOX 200 55216 Ingelheim Am Rhein Germany	bromhexine hydrochloride	BISOLVON	0,8 mg/ml	oral solution	oral use
Finland	Boehringer Ingelheim International GmbH Binger Strasse 173 P.O. BOX 200 55216 Ingelheim Am Rhein Germany	bromhexine hydrochloride	BISOLVON	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Finland	Boehringer Ingelheim International GmbH Binger Strasse 173 P.O. BOX 200 55216 Ingelheim Am Rhein Germany	bromhexine hydrochloride	BISOLVON	8 mg	soluble tablet	oral use
Finland	Boehringer Ingelheim International GmbH Binger Strasse 173 P.O. BOX 200 55216 Ingelheim Am Rhein Germany	bromhexine hydrochloride	BISOLVON	8 mg	oral solution, sachet	oral use
Finland	Boehringer Ingelheim International GmbH Binger Strasse 173 P.O. BOX 200 55216 Ingelheim Am Rhein Germany	bromhexine hydrochloride	BISOLVON STRONG	1,6 mg/ml	oral solution	oral use
Finland	Orion Oyj Orionintie 1 PL 65 02101 ESPOO Finland	bromhexine hydrochloride	MEDIPEKT	0,8 mg/ml	oral solution	oral use
Finland	Orion Oyj Orionintie 1 PL 65 02101 ESPOO Finland	bromhexine hydrochloride	MEDIPEKT	8 mg	tablet	oral use
Finland	Oy Leiras Takeda Paciuksenkatu 21 PL 1406 00101 HELSINKI Finland	bromhexine hydrochloride	MUCOVIN	0,8 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	Laboratoires de l'AEROCID 248 bis, rue Gabriel Péri B.P. 126 94232 Cachan Cedex France	ambroxol (chlorhydrate d')	AMBROXOL AEROCID 0,6 %, solution buvable	0,6 g per 100 ml of solution	oral solution	oral use
France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon France	ambroxol (chlorhydrate d')	AMBROXOL ARROW 0,6 %, solution buvable	0,6 g per 100 ml of solution	oral solution	oral use
France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon France	ambroxol (chlorhydrate d')	AMBROXOL ARROW 30 mg, comprimé	30 mg	tablet	oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes France	ambroxol (chlorhydrate d')	AMBROXOL BIOGARAN CONSEIL 0,6 % SANS SUCRE, solution buvable édulcorée au sorbitol	0,6 g per 100 ml of solution	oral solution	oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes France	ambroxol (chlorhydrate d')	AMBROXOL BIOGARAN CONSEIL 30 mg, comprimé sécable	30 mg	tablet	oral use
France	EG LABO — Laboratoires EuroGenerics 'Le Quintet' — bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ambroxol (chlorhydrate d')	AMBROXOL EG 0,3 POUR CENT SANS SUCRE, solution buvable édulcorée au cyclamate de sodium et au sorbitol	0,3 g per 100 ml of solution	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	EG LABO — Laboratoires EuroGenerics 'Le Quintet' — bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ambroxol (chlorhydrate d')	AMBROXOL EG 0,6 %, solution buvable	0,6 g per 100 ml of solution	oral solution	oral use
France	EG LABO — Laboratoires EuroGenerics 'Le Quintet' — bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	ambroxol (chlorhydrate d')	AMBROXOL EG 30 mg, comprimé sécable	30 mg	tablet	oral use
France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest France	ambroxol (chlorhydrate d')	AMBROXOL MYLAN 0,6 %, solution buvable	0,6 g per 100 ml of solution	oral solution	oral use
France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest France	ambroxol (chlorhydrate d')	AMBROXOL MYLAN 30 mg, comprimé	30 mg	tablet	oral use
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret France	ambroxol (chlorhydrate d')	AMBROXOL SANDOZ CONSEIL 0,6 % SANS SUCRE, solution buvable édulcorée à la saccharine sodique	0,6 g per 100 ml of solution	oral solution	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	ambroxol (chlorhydrate d')	AMBROXOL TEVA CONSEIL 0,3 %, solution buvable	0,3 g per 100 ml of solution	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	ambroxol (chlorhydrate d')	AMBROXOL TEVA CONSEIL 0,6 %, solution buvable	0,6 g per 100 ml of solution	oral solution	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	ambroxol (chlorhydrate d')	AMBROXOL TEVA CONSEIL 30 mg, comprimé	30 mg	tablet	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	ambroxol (chlorhydrate d')	VICKS EXPECTORANT AMBROXOL 0,6 %, solution buvable	0,6 g per 100 ml of solution	oral solution	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex France	ambroxol (chlorhydrate d')	VICKS EXPECTORANT AMBROXOL 30 mg, comprimé sécable	30 mg	tablet	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	LYSOPAÏNE MAUX DE GORGE AMBROXOL CASSIS 20 mg SANS SUCRE, pastille édulcorée au sorbitol et au sucralose	20 mg	lozenge	oromucosal use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	LYSOPAÏNE MAUX DE GORGE AMBROXOL CITRON 20 mg SANS SUCRE, pastille édulcorée au sorbitol et au sucralose	20 mg	lozenge	oromucosal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	LYSOPAÏNE MAUX DE GORGE AMBROXOL MENTHE 20 mg SANS SUCRE, pastille édulcorée au sorbitol et au sucralose	20 mg	lozenge	oromucosal use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	SURBRONC 60 mg, comprimé enrobé sécable	60 mg	tablet	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	SURBRONC 60 mg, granulés pour solution buvable en sachet	60 mg	granules for oral solution	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	SURBRONC EXPECTORANT AMBROXOL 30 mg, comprimé sécable	30 mg	tablet	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	SURBRONC EXPECTORANT AMBROXOL SANS SUCRE, solution buvable édulcorée à l'acésulfame potassique et au sorbitol	0,600 g per 100 ml of solution	oral solution	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	ambroxol (chlorhydrate d')	SURBRONC L.P. 75 mg, gélule à libération prolongée	75 mg	hard capsule, prolonged relase	oral use
France	BIOCODEX 7, avenue Gallieni 94250 Gentilly France	ambroxol (chlorhydrate d')	MUXOL 30 mg, comprimé	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
France	BIOCODEX 7, avenue Gallieni 94250 Gentilly France	ambroxol (chlorhydrate d')	MUXOL, solution buvable	0,3 g per 100 ml of solution	oral solution	oral use
France	CHRIS PHARMAZEUTISCHE HANDELS-GESELLSCHAFT mbH Weg im Esterholz 6 82064 Strasslach Germany	ambroxol (chlorhydrate d')	MUXOL 60 mg, comprimé effervescent	60 mg	effervescent tablet	oral use
France	RECKITT BENCKISER HEALTHCARE France 15, rue Ampère 91748 Massy Cedex France	ambroxol (chlorhydrate d')	STREPSILS EXPECTORANT 30 mg/5 ml ADULTES, sirop	30 mg per 5 ml of syrup	syrup	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	bromhexine (chlorhydrate de)	BISOLVON 0,2 POUR CENT, solution buvable	200 mg per 100 ml of solution	oral solution	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	bromhexine (chlorhydrate de)	BISOLVON 8 mg, comprimé	8 mg per tablet	tablet	oral use
France	BOEHRINGER INGELHEIM FRANCE 14, rue Jean Antoine de Baïf 75013 Paris France	bromhexine (chlorhydrate de); tétracycline (chlorhydrate de)	BISOLVOMYCINE, comprimé enrobé	4 mg per tablet	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	1 A Pharma Keltenring 1 + 3 82041 Oberhaching Germany	Ambroxol hydrochloride	Ambroxol 15 Saft — 1A Pharma	0,3 g	oral solution	oral use
Germany	1 A Pharma Keltenring 1 + 3 82041 Oberhaching Germany	Ambroxol hydrochloride	Ambroxol 30 Saft — 1A Pharma	6 mg	oral solution	oral use
Germany	1 A Pharma Keltenring 1 + 3 82041 Oberhaching Germany	Ambroxol hydrochloride	Ambroxol 30 Tab — 1A Pharma	30 mg	tablet	oral use
Germany	1 A Pharma Keltenring 1 + 3 82041 Oberhaching Germany	Ambroxol hydrochloride	Ambroxol 30 Tropfen — 1A Pharma	15 mg	oral drops, solution	oral use
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambro-AbZ 3 mg/ml Lösung zum Einnehmen	3 mg	oral solution	oral use
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol AbZ Hustensaft 15 mg/5 ml Lösung zum Einnehmen	15 mg/5 ml	oral solution	oral use
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-CT Tropfen	7,5 mg	oral drops, solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride, Doxycycline hycalate	Doxy comp.-CT 100 mg/75 mg Retardkapseln	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambro-AbZ 6 mg/ml Lösung zum Einnehmen	6 mg/ml	oral solution	oral use
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambro-CT 3 mg/ml Lösung zum Einnehmen	3 mg/ml	oral solution	oral use
Germany	AbZ Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol AbZ 75 mg Retardkapseln	75 mg	prolonged-release capsule, hard	oral use
Germany	acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grünwald Germany	Ambroxol hydrochloride	Ambroxol acis Tropfen	7,5 mg	oral solution	oral use
Germany	acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grünwald Germany	Ambroxol hydrochloride	Ambroxol acis 60 mg Brausetabletten	60 mg	effervescent tablet	oral use
Germany	acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grünwald Germany	Ambroxol hydrochloride	Ambroxol acis Saft	15 mg	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	acis Arzneimittel GmbH Lil-Dagover-Ring 7 82031 Grünwald Germany	Ambroxol hydrochloride	Ambroxol acis 30 mg Trinktabletten	30 mg	soluble tablet	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Ambroxol hydrochloride	Ambroxol AL 30	30 mg	tablet	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Ambroxol hydrochloride, Doxycycline hycalate	Ambroxol AL comp	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Ambroxol hydrochloride	Ambroxol AL Saft	15 mg	oral solution	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Ambroxol hydrochloride	Ambroxol AL 75 retard	75 mg	prolonged-release capsule, hard	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Ambroxol hydrochloride	Ambroxol AL Tropfen	7,5 mg	oral drops, solution	oral use
Germany	Aliud Pharma GmbH Gottlieb-Daimler-Str. 19 89150 Laichingen Germany	Ambroxol hydrochloride	Ambroxol AL 60 mg Brausetabletten	60 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Ambroxol hydrochloride	Ambroxol Aristo Hustentropfen 15 mg/ml	15 mg	oral solution	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Ambroxol hydrochloride	Ambroxol Aristo Hustentropfen für Kinder 7,5 mg/ml	7,5 mg	oral solution	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Ambroxol hydrochloride, Doxycycline hycalate	Doxam 100 mg/75 mg Hartkapsel retardiert	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Ambroxol hydrochloride	Ambroxol Aristo Hustensaft 30 mg/5 ml	30 mg/5 ml	oral solution	oral use
Germany	axcount Generika GmbH Max-Planck. Str. 36 b 61381 Friedrichsdorf Germany	Ambroxol hydrochloride	Ambroxol axcount Saft	15 mg	oral solution	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed Hustensaft 30 mg/5 ml Lösung zum Einnehmen	30 mg/5 ml	oral solution	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed Hustenlöser 30 mg/5 ml Lösung zum Einnehmen	30 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Bromhexine hydrochloride	BROMHEXIN 12 BC	12 mg	oral drops, solution	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Bromhexine hydrochloride	BROMHEXIN 4 BC	4 mg	oral solution	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed Hustensaft	15 mg	oral solution	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed Hustentabletten	30 mg	tablet	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Bromhexine hydrochloride	BROMHEXIN 8 Berlin-Chemie	8 mg	coated tablet	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed Hustensaft 15 mg/5 ml Lösung zum Einnehmen	15 mg	oral solution	oral use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed 60 mg Brausetabletten	60 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	betapharm Arzneimittel GmbH Kobelweg 95 86156 Augsburg Germany	Ambroxol hydrochloride	Ambrobeta 30	30 mg	effervescent tablet	oral use
Germany	betapharm Arzneimittel GmbH Kobelweg 95 86156 Augsburg Germany	Ambroxol hydrochloride	Ambrobeta Saft	3 mg	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Filmtabletten 60 mg	60 mg	film-coated tablet	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Retardkapseln 75 mg	75 mg	prolonged-release capsule, hard	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride, Clenbuterol hydrochloride	Spasmo-Mucosolvan Saft	7,5 mg, 0,005 mg	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucoangin gegen Halsschmerzen 20 mg Pastillen	20 mg	pastille	oromucosal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucoangin gegen Halsschmerzen Zitrone 20 mg Lutschtabletten	20 mg	lozenge	oromucosal use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucoangin gegen Halsschmerzen Minze	20 mg	lozenge	oromucosal use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Hustensaft 30 mg/5 ml	30 mg/5 ml	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Inhalationslösung 15 mg/2 ml	15 mg/2 ml	nebuliser solution	inhalation use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Tabletten 30 mg	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Infusionslösungskonzentrat	1 mg	concentrate for solution for infusion	intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Brausetabletten 60 mg	60 mg	effervescent tablet	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Bromhexine hydrochloride	Bisolvon Hustentropfen	2 mg	oral drops, solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Kindersaft 30 mg/5 ml	30 mg/5 ml	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Tropfen 30 mg/2 ml	30 mg/2 ml	oral drops, solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Tropfen 30 mg/2 ml	30 mg/2 ml	oral drops, solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Injektionslösung	15 mg	solution for injection	intravenous use, intramuscular use, subcutaneous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucoangin gegen Halsschmerzen Waldbeere	20 mg	lozenge	oromucosal use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Lutschpastillen 15 mg	15 mg	pastille	oromucosal use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Ambroxol 60 mg	60 mg	granules for oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Bromhexine hydrochloride	Bisolvon-Linctus Hustensaft	0,08 g/100 ml	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Bromhexine hydrochloride	Bisolvon Hustentabletten	8 mg	tablet	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Kindersaft 15 mg/5 ml	15 mg	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan Portionsbeutel 30 mg/5 ml	30 mg	oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Ambroxol Portionsbeutel 30 mg/5 mg	30 mg	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Mucosolvan 60 mg	60 mg	granules for oral solution	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride	Bisolaryn gegen Halzschmerzen 20 mg Pastillen	20 mg	pastille	oromucosal use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Ambroxol hydrochloride, Clenbuterol hydrochloride	Spasmo-Mucosolvan	30 mg, 0,02 mg	tablet	oral use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Bromhexine hydrochloride	Bisolvon Hustensaft	8 mg	oral solution	oral use
Germany	Cyathus Exquirere Pharmaforschungs GmbH Rudolfplatz 2/1/8 1010 Wien Austria	Ambroxol hydrochloride	Ambroxolhydrochloride Cyathus 10 mg/ Sprühstoß Lösung zum Einnehmen	10 mg	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Cyathus Exquirere Pharmaforschungs GmbH Rudolfplatz 2/1/8 1010 Wien Austria	Ambroxol hydrochloride	Mukambro 10 mg/Sprühstoß Lösung zum Einnehmen	10 mg	oral solution	oral use
Germany	Denk Pharma GmbH & Co. KG Prinzregentenstr. 79 81675 München Germany	Ambroxol hydrochloride	Ambrox-Denk 60 mg	60 mg	effervescent tablet	oral use
Germany	Divapharma GmbH Motzener Str. 41 12277 Berlin Germany	Ambroxol hydrochloride	Neo-bronchol	15 mg	oral gum	oral use
Germany	Docpharm Arzneimittelvertrieb GmbH & Co. KG Greschbachstr. 7 76229 Karlsruhe Germany	Ambroxol hydrochloride	Ambroxol PB 30 mg	30 mg	film-coated tablet	oral use
Germany	Dr. Ritsert Pharma GmbH & Co. KG Klausenweg 12 69412 Eberbach Germany	Ambroxol hydrochloride	Expit T Tropfen	7,5 mg	oral drops, solution	oral use
Germany	Dr. Ritsert Pharma GmbH & Co. KG Klausenweg 12 69412 Eberbach Germany	Ambroxol hydrochloride	Expit Lösung	15 mg	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	esparma GmbH Seepark 7 39116 Magdeburg Germany	Ambroxol hydrochloride, Doxycycline hycalate	Sigamuc	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	Aristo Pharma GmbH Wallenroder Str. 8-10 13435 Berlin Germany	Ambroxol hydrochloride	Ambroxin-Tropfen	7,5 mg	oral drops, solution	oral use
Germany	Hemopharm GmbH Königsteiner Str. 2 61350 Bad Homburg v.d.H. Germany	Ambroxol hydrochloride	Ambro-Hemopharm Hustensaft	15 mg	prolonged-release capsule, hard	oral use
Germany	Hermes Arzneimittel GmbH Georg-Kalb-Str. 5-8 82049 Großhesselohe Germany	Ambroxol hydrochloride	Ambroxo Brause 1 Hermes	30 mg	effervescent tablet	oral use
Germany	Hermes Arzneimittel GmbH Georg-Kalb-Str. 5-8 82049 Großhesselohe Germany	Ambroxol hydrochloride	Ambroxo Hermes 60 mg	60 mg	effervescent tablet	oral use
Germany	Hermes Arzneimittel GmbH Georg-Kalb-Str. 5-8 82049 Großhesselohe Germany	Ambroxol hydrochloride	Ambroxol Brause 60	60 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Heumann Pharma GmbH&Co. KG Generica KG Südwestpark 50 90449 Nürnberg Germany	Ambroxol hydrochloride	Ambroxol Heumann Saft	3 mg	oral solution	oral use
Germany	Heumann Pharma GmbH&Co. KG Generica KG Südwestpark 50 90449 Nürnberg Germany	Ambroxol hydrochloride	Ambroxol Heumann Tropfen	7,5 mg	oral drops	oral use
Germany	Heumann Pharma GmbH&Co. KG Generica KG Südwestpark 50 90449 Nürnberg Germany	Ambroxol hydrochloride	Ambroxol 75 retard Heumann	75 mg	prolonged-release capsule, hard	oral use
Germany	Heumann Pharma GmbH&Co. KG Generica KG Südwestpark 50 90449 Nürnberg Germany	Ambroxol hydrochloride	Ambroxol 60 Heumann Brausetabletten	60 mg	effervescent tablet	oral use
Germany	Heumann Pharma GmbH&Co. KG Generica KG Südwestpark 50 90449 Nürnberg Germany	Ambroxol hydrochloride	Ambroxol 30 Heumann	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal injekt	15 mg	solution for injection	intravenous use, intramuscular use, subcutaneous use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	AmbroHEXAL Hustensaft für Kinder	3 mg	oral solution	oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	AmbroHEXAL Hustenlöser 30 mg Tabletten	30 mg	tablet	oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal Hustenlöser retard 75 mg	75 mg	prolonged-release capsule, hard	oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal S Hustensaft 30 mg/5 ml	6 mg	oral solution	oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal S Hustentropfen 15 mg/ml	15 mg	oral solution	oral use
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal S Hustenlöser 60 mg Filmtabletten	60 mg	film-coated tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Hexal Aktiengesellschaft Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal Hustenlöser Brausetabletten	60 mg	effervescent tablet	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Ambroxol hydrochloride	Ambroxol Krewel Meuselbach Tropfen 7,5 mg/ml	7,5 mg	oral drops, solution	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Bromhexine hydrochloride	Bromhexin Krewel Meuselbach Tabletten 12 mg	12 mg	tablet	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Bromhexine hydrochloride	Bromhexin Krewel Meuselbach Tropfen 12 mg	12 mg	oral drops, solution	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Bromhexine hydrochloride	Bromhexin Krewel Meuselbach Tropfen 8 mg	8 mg	oral drops, solution	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Ambroxol hydrochloride	Ambroxol Krewel Meuselbach Sirup 15 mg/5 ml	15 mg	syrup	oral use
Germany	Krewel Meuselbach GmbH Krewelstr. 2 53783 Eitorf Germany	Bromhexine hydrochloride	Bromhexin Krewel Meuselbach Hustensaft 8 mg/10 ml	0,8 mg	solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Meda Pharma GmbH&Co. KG Benzstr. 1 61352 Bad Homburg Germany	Ambroxol hydrochloride	Lindoxyl K Zäpfchen	15 mg	suppository	rectal use
Germany	Pädia Arzneimittel Gruhlstr. 3 50374 Erftstadt Germany	Ambroxol hydrochloride	Pädiamuc Saft	15 mg	oral solution	oral use
Germany	Pharma Stulln GmbH Werkstr. 3 92551 Stulln Germany	Ambroxol hydrochloride	Ambroxol Inhalat	7,5 mg/ml	nebuliser solution	inhalation use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm Hustentropfen	7,5 mg	oral drops, solution	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 15 mg/2 ml Injektionslösung	15 mg	solution for injection	intravenous use, intramuscular use, subcutaneous use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambro-ratiopharm 3 mg/ml Lösung zum Einnehmen	3 mg	oral solution	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 75 mg Hustenlöser	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 30 mg Hustenlöser	30 mg	tablet	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm Hustensaft	15 mg	oral solution	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambro-ratiopharm 6 mg/ml Lösung zum Einnehmen	6 mg	oral solution	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol, Doxycycline	Ambroxol comp.-ratiopharm 75 mg/ 100 mg Retardkapseln	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 60 mg Hustenlöser	60 mg	tablet	oral use
Germany	RubiePharm Vertiebs GmbH Sennelsbachweg 4 36396 Stainau an der Strasse Germany	Ambroxol hydrochloride	AMBROinfant	15 mg	oral solution	oral use
Germany	Sandoz Phamaceuticals GmbH Raiffeisenstr. 11 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambroxol Sandoz 7,5 mg/ml Tropfen zum Einnehmen, Lösung	7,5 mg	oral drops, solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Sandoz Phamaceuticals GmbH Raiffeisenstr. 11 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambroxol Sandoz 15 mg/5 ml Lösung zum Einnehmen	15 mg	oral solution	oral use
Germany	Sandoz Phamaceuticals GmbH Raiffeisenstr. 11 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambroxol Sandoz 30 mg Tabletten	30 mg	tablet	oral use
Germany	Stadapharm GmbH Saalstr. 2.18 61118 Bad Vilbel Germany	Ambroxol hydrochloride	Ambroxol Stada Hustensaft 15 mg/5 ml, Lösung zum Einnehmen	15 mg	solution	oral use
Germany	Stadapharm GmbH Saalstr. 2.18 61118 Bad Vilbel Germany	Ambroxole, Doxycycline hyclate	Doxy plus STADA 100 mg/75 mg Hartkapseln, retardiert	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	TAD Pharma GmbH Heinz-Lohmann-Str. 5 27472 Cuxhaven Germany	Ambroxol hydrochloride, Doxycycline hyclate	Doxam	75 mg, 115,4 mg	prolonged-release capsule, hard	oral use
Germany	Takeda GmbH Byk-Gulden-Str. 2 78467 Konstanz Germany	Ambroxol hydrochloride Theophylline	Broncho-Euphyllin retard	30 mg, 350 mg	prolonged-release capsule, hard	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol Temmler 75 mg Retardkapseln	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Axol 60 mg Brausetabletten	60 mg	effervescent tablet	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol retard Temmler	75 mg	prolonged-release capsule, hard	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol Temmler Tropfen	7,5 mg	oral drops, solution	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol Temmler Saft	15 mg	oral solution	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Braxol 60 mg Brausetabletten	60 mg	effervescent tablet	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol Temmler 30 mg Brausetabletten	30 mg	effervescent tablet	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol 7,5 TT Temmler Trinktabletten	7,5 mg	soluble tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol 15 TT Temmler Trinktabletten	15 mg	soluble tablet	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol 30 TT Temmler Trinktabletten	30 mg	tablet	oral use
Germany	Temmler Pharma GmbH&Co. KG Temmlerstr. 2 35039 Marburg Germany	Ambroxol hydrochloride	Ambroxol Temmler 60 mg Brausetabletten	60 mg	effervescent tablet	oral use
Germany	Wick Pharma Zweigniederlassung Procter & Gamble GmbH Sulzbacher Str. 40 65824 Schwalbach/Taunus Germany	Ambroxol hydrochloride	Ambroxol WICK Schleimlöser für Kinder 3 mg/ml Lösung zum Einnehmen	15 mg	oral solution	oral use
Germany	Wick Pharma Zweigniederlassung Procter & Gamble GmbH Sulzbacher Str. 40 65824 Schwalbach/Taunus Germany	Ambroxol hydrochloride	Wick Schleimlöser 30 mg Tabletten	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Germany	Wick Pharma Zweigniederlassung Procter & Gamble GmbH Sulzbacher Str. 40 65824 Schwalbach/Taunus Germany	Ambroxol hydrochloride	Wick Schleimlöser 6 mg/ml Lösung zum Einnehmen	6 mg	oral solution	oral use
Germany	Wick Pharma Zweigniederlassung Procter & Gamble GmbH Sulzbacher Str. 40 65824 Schwalbach/Taunus Germany	Ambroxol hydrochloride	Wick Schleimlöser 30 mg Brausetabletten	30 mg	effervescent tablet	oral use
Germany	Wick Pharma Zweigniederlassung Procter & Gamble GmbH Sulzbacher Str. 40 65824 Schwalbach/Taunus Germany	Ambroxol hydrochloride	Wick Hustenlöser Therapie	30 mg	effervescent tablet	oral use
Germany	Wick Pharma Zweigniederlassung Procter & Gamble GmbH Sulzbacher Str. 40 65824 Schwalbach/Taunus Germany	Ambroxol hydrochloride	Wick Schleimlöser 75 Einmal Täglich Retardkapseln	75 mg	prolonged-release capsule, hard	oral use
Greece	Adelco A.E. Chrom. Athin. Afoi Kolokotroni, Peireos 37, Moschato, Greece	BROMHEXINE	Bronchotussine	4 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Alapis Abee, Aftokratoros Nikolaou 2, 11745, Athens, Greece	AMBROXOL HYDROCHLORIDE	Amboral	15 mg/5 ml	syrup	oral use
Greece	Alapis Abee, Aftokratoros Nikolaou 2, 11745, Athens, Greece	AMBROXOL HYDROCHLORIDE	Amboral	30 mg/5 ml	syrup	oral use
Greece	Angelini Pharma Hellas Anonimi Biomhxaniki Etaireia Paragogis & Emporias Farmakon, Achaias & Trizinias, 14564, N. Kiffisia, Greece	AMBROXOL HYDROCHLORIDE	Tussefar	15 mg/5 ml	syrup	oral use
Greece	Angelini Pharma Hellas Anonimi Biomhxaniki Etaireia Paragogis & Emporias Farmakon, Achaias & Trizinias, 14564, N. Kiffisia, Greece	AMBROXOL HYDROCHLORIDE	Tussefar	30 mg/5 ml	syrup	oral use
Greece	Boehringer Ingelheim Ellas Aε, Ellinikou 2, 16777, Ellinikon, Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	75 mg	prolonged-release capsule	oral use
Greece	Boehringer Ingelheim Ellas Aε, Ellinikou 2, 16777, Ellinikon, Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	15 mg/2 ml	solution for injection	intravenous use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	30 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	30 mg	tablet	oral use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	BROMHEXINE	Bisolvon	8 mg	tablet	oral use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	15 mg/2 ml	solution for injection	intramuscular use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	BROMHEXINE	Bisolvon	8 mg	soluble tablet	oral use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	BROMHEXINE	Bisolvon	4 mg/5 ml	syrup	oral use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	BROMHEXINE	Bisolvon	8 mg/5 ml	syrup	oral use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	15 mg	oral gum	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	15 mg/2 ml	solution for injection	intravenous use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Mucosolvan	15 mg/5 ml	syrup	oral use
Greece	Boehringer Ingelheim Ellas AE, Ellinikou 2, 16777, Ellinikon, Athens Greece	AMBROXOL HYDROCHLORIDE	Lysopadol	20 mg	lozenge	oromucosal use
Greece	Bros E.P.E., Aygis & Galinis 15, 14564, Nea Kifissia, Greece	AMBROXOL HYDROCHLORIDE	Ebertuss	30 mg/5 ml	syrup	oral use
Greece	Coup Abee, Ag. Barbaras 53-55, 17235 Dafni, Greece	AMBROXOL HYDROCHLORIDE	Nibren	30 mg/5 ml	syrup	oral use
Greece	D.A.S.T. Biotech Φαρ/Κη Επε Δ.Τ. D.A.S.T. Biotech Pharm Επε, Λαρίσσης 10, 15351 Athens, Greece	AMBROXOL HYDROCHLORIDE	Provixen-N	30 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Elpen Ae Φαρμακευτικη Βιομηχανια, Leof. Marathonos 95, 19009 Pikermi, Greece	AMBROXOL HYDROCHLORIDE	Celibron	30 mg	tablet	oral use
Greece	Elpen Ae Φαρμακευτικη Βιομηχανια, Leof. Marathonos 95, 19009 Pikermi, Greece	AMBROXOL HYDROCHLORIDE	Celibron	30 mg/5 ml	syrup	oral use
Greece	Elpen Ae Φαρμακευτικη Βιομηχανια, Leof. Marathonos 95, 19009 Pikermi, Greece	AMBROXOL HYDROCHLORIDE	Celibron	15 mg/5 ml	syrup	oral use
Greece	Farmellas Enterprises Ltd, Cyprus, Leof. Afxentiou 27, Acropolis Centre, Cyprus	AMBROXOL HYDROCHLORIDE	Fluibrox	30 mg/5 ml	syrup	oral use
Greece	Genepharm Ae, 18 Km. Leof. Marathonos, 15351 Pallini, Greece	AMBROXOL HYDROCHLORIDE	Grenovix	30 mg/5 ml	syrup	oral use
Greece	Genepharm Ae, 18 Km. Leof. Marathonos, 15351 Pallini, Greece	AMBROXOL HYDROCHLORIDE	Grenovix	30 mg	tablet	oral use
Greece	Help Αβεε, Valaoritou 10, 14452, Metamorfosi, Greece	AMBROXOL HYDROCHLORIDE	Abrobion	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Help Αβεε, Valaoritou 10, 14452, Metamorfosi, Greece	AMBROXOL HYDROCHLORIDE	Abrobion	30 mg/5 ml	syrup	oral use
Greece	Help Αβεε, Valaoritou 10, 14452, Metamorfosi, Greece	AMBROXOL HYDROCHLORIDE	Abrobion	15 mg/5 ml	syrup	oral use
Greece	Help Αβεε, Valaoritou 10, 14452, Metamorfosi, Greece	BROMHEXINE	Bron-Hal	4 mg/5 ml	syrup	oral use
Greece	Iasis Pharmac. Hellas Biom. & Emp F/Kon-Chem/Kon & Kal. Pr. Abee, L. Fylis 137, 13451 Kamatero Attikis, Greece	AMBROXOL HYDROCHLORIDE	Afrodor	30 mg/5 ml	syrup	oral use
Greece	Novendia Farmakeytiki Epe, Leof. Irakliou 425 & Olympias 28, 14122 N. Iraklio, Greece	AMBROXOL HYDROCHLORIDE	Tevoril	30 mg/5 ml	syrup	oral use
Greece	Pharmaswiss Ceska Republika s.r.o., Jancovcova 1569/2c, 1700 Praha 7, Holesovice, Czech Republic	AMBROXOL HYDROCHLORIDE	Physiosolvan	30 mg/5 ml	syrup	oral use
Greece	Pharmaswiss Ceska Republika s.r.o., Jancovcova 1569/2c, 1700 Praha 7, Holesovice, Czech Republic	AMBROXOL HYDROCHLORIDE	Physiosolvan	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Rafarm, 12, Korinthou Str., New Psychico, Athens 15451, Greece	AMBROXOL HYDROCHLORIDE	Kriolen	30 mg/5 ml	syrup	oral use
Greece	S.J.A. Pharm Farmakeytiki E.P.E 11 Arkoleon Str., Patissia 10445, Greece	AMBROXOL HYDROCHLORIDE	Stefolant	30 mg/5 ml	syrup	oral use
Greece	Ανφαρμ Ellas A.E., Perikleous 53-57 Gerakas 15344, Greece	AMBROXOL HYDROCHLORIDE	Aprinol	30 mg/5 ml	syrup	oral use
Greece	Ανφαρμ Ellas A.E., Perikleous 53-57 Gerakas 15344, Greece	AMBROXOL HYDROCHLORIDE	Aprinol	15 mg/5 ml	syrup	oral use
Greece	Vianex A.E., Tatoiou Street, 18th Km National Road Athens-Lamia, 14571 Nea Erythrea, Greece	AMBROXOL HYDROCHLORIDE	Broncolyn	30 mg/tab	tablet	oral use
Greece	Vianex A.E., Tatoiou Street, 18th Km National Road Athens-Lamia, 14571 Nea Erythrea, Greece	AMBROXOL HYDROCHLORIDE	Broncolyn	30 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Vianex A.E., Tatoiou Street, 18th Km National Road Athens-Lamia, 14571 Nea Erythrea, Greece	AMBROXOL HYDROCHLORIDE	Broncolyn	15 mg/5 ml	syrup	oral use
Greece	Exelixi Emporia Iatr. Eidon A.E., L. Mesogeion 501, 15343 Athens, Greece	AMBROXOL HYDROCHLORIDE	Saribal	15 mg/5 ml	syrup	oral use
Greece	Exelixi Emporia Iatr. Eidon A.E., L. Mesogeion 501, 15343 Athens, Greece	AMBROXOL HYDROCHLORIDE	Saribal	30 mg/5 ml	syrup	oral use
Greece	Ioul. & Eir. Tseti Far/Ka Ergastiria Abee, Kalyftaki 27, 14561 Kifissia, Attiki, Greece	AMBROXOL HYDROCHLORIDE	Bunafon	15 mg/5 ml	syrup	oral use
Greece	Ioul. & Eir. Tseti Far/Ka Ergastiria Abee, Kalyftaki 27, 14561 Kifissia, Attiki, Greece	AMBROXOL HYDROCHLORIDE	Bunafon	30 mg/5 ml	syrup	oral use
Greece	Ioul. & Eir. Tseti Far/Ka Ergastiria Abee, Kalyftaki 27, 14561 Kifissia, Attiki, Greece	AMBROXOL HYDROCHLORIDE	Bunafon	15 mg	granules for oral solution in sachet	oral use
Greece	Ioul. & Eir. Tseti Far/Ka Ergastiria Abee, Kalyftaki 27, 14561 Kifissia, Attiki, Greece	AMBROXOL HYDROCHLORIDE	Bunafon	30 mg	granules for oral solution in sachet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Greece	Koper Farmakoviomihania A.E., Aristovoulou 64, 11853 Athens, Greece	AMBROXOL HYDROCHLORIDE	Mucolin	30 mg/5 ml	syrup	oral use
Greece	Koper Farmakoviomihania A.E., Aristovoulou 64, 11853 Athens, Greece	AMBROXOL HYDROCHLORIDE	Mucolin	15 mg/5 ml	syrup	oral use
Greece	S.M. Farmakeytika Proionta Epe, Agiou Orous 43-45, 18545 Peireas, Atiiki, Greece	AMBROXOL HYDROCHLORIDE	Mucovix	30 mg/5 ml	syrup	oral use
Greece	Foinixfarm Epe, Dervenakion 38 & Sahini, 15344, Gerakas, Greece	AMBROXOL HYDROCHLORIDE	Strubelin	30 mg/5 ml	syrup	oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROBENE 7,5 mg/ml belsőleges oldat	7,5 mg/ml	oral solution	oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROBENE 15 mg/5 ml szirup	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROBENE 30 mg tabletta	30 mg	tablet	oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROBENE 7,5 mg/ml oldatos injekció	7,5 mg/ml	solution for injection	intravenous use, intramuscular use, subcutaneous use
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROXOL TEVA 6 mg/ml belsőleges oldat	6 mg/ml	oral solution	oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROXOL-TEVA 3 mg/ml szirup	3 mg/ml	syrup	oral use
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROXOL-TEVA 30 mg tabletta	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	Teva Gyógyszergyár Zrt. Pallagi út 13 Debrecen H-4042 Hungary	ambroxol	AMBROXOL-TEVA 75 mg retard kemény kapszula	75 mg	prolonged-release capsule, hard	oral use
Hungary	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 Berlin D-12489 Germany	ambroxol	FLAVAMED 15 mg/5 ml belsőleges oldat	15 mg/5 ml	oral solution	oral use
Hungary	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 Berlin D-12489 Germany	ambroxol	FLAVAMED 30 mg tabletta	30 mg	tablet	oral use
Hungary	Berlin-Chemie AG (Menarini Group) Glienicker Weg 125 Berlin D-12489 Germany	ambroxol	FLAVAMED 30 mg/5 ml belsőleges oldat	30 mg/5 ml	oral solution	oral use
Hungary	EGIS Gyógyszergyár Zrt., Keresztúri út 30-38. Budapest H-1106 Hungary	ambroxol	HALIXOL 30 mg tabletta	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	EGIS Gyógyszergyár Zrt., Keresztúri út 30-38. Budapest H-1106 Hungary	ambroxol	HALIXOL 3 mg/ml szirup	0,3 g/100 ml	syrup	oral use
Hungary	Boehringer Ingelheim International GmbH Binger strasse 173 55216 Ingelheim am Rhein Germany	ambroxol	MUCOANGIN 20 mg szopogató tabletta	20 mg	lozenge	oromucosal use
Hungary	Pharma-Regist Kft., Október 6. u. 7. Budapest 1051 Hungary	ambroxol	MUCOFREE 15 mg/5 ml szirup	15 mg/5 ml	syrup	oral use
Hungary	Pharma-Regist Kft., Október 6. u. 7. Budapest 1051 Hungary	ambroxol	MUCOFREE 30 mg/5 ml szirup	30 mg/5 ml	syrup	oral use
Hungary	PannonPharma Kft. Pannonpharma út 1. Pécsvárad H-7720 Hungary	ambroxol	MUKAMBRO 10 mg/adag belsőleges oldatos spray	10 mg/dose	oromucosal spray	oromucosal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	Divapharma GmbH Motzener Str. 41 D-12277 Berlin Germany	ambroxol	NEO-BRONCHOL szopogató tabletta	15 mg	lozenge	oromucosal use
Hungary	Meditop Gyógyszeripari Kft. Ady Endre u. 1 Pilisborosjenő H-2097 Hungary	bromhexine, oxymetazoline	NASOPAX orrspray felnőtteknek	0,12 mg/0,025 mg oximetazolin-klorid/dose (0,1 ml).	nasal spray, solution	nasal use
Hungary	Meditop Gyógyszeripari Kft. Ady Endre u. 1 Pilisborosjenő H-2097 Hungary	bromhexine, oxymetazoline	NASOPAX orrspray gyermekeknek	0,06 mg/0,005 mg oximetazolin-klorid/dose (0,1 ml).	nasal spray, solution	nasal use
Hungary	EGIS Gyógyszergyár Zrt., Keresztúri út 30-38. Budapest H-1106 Hungary	bromhexine	PAXIRASOL 2 mg/ml belsőleges oldat	2 mg/ml	oral solution	oral use
Hungary	EGIS Gyógyszergyár Zrt., Keresztúri út 30-38. Budapest H-1106 Hungary	bromhexine	PAXIRASOL 2 mg/ml oldatos injekció	2 mg/ml	solution for injection	intravenous use, intramuscular use, subcutaneous use
Hungary	EGIS Gyógyszergyár Zrt., Keresztúri út 30-38. Budapest H-1106 Hungary	bromhexine	PAXIRASOL 8 mg tabletta	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Hungary	EGIS Gyógyszergyár Zrt., Keresztúri út 30-38. Budapest H-1106 Hungary	bromhexine	PAXIRASOL oldatos orrspray	0,2 mg/dose	nasal spray, solution	nasal use
Iceland	Boehringer Ingelheim International G.m.b.H., Binger Strasse 173, 55216 Ingelheim am Rhein, Germany	Bromhexinum INN chloride	Bisolvon	8 mg	tablet	oral use
Ireland	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Ambroxol hydrochloride	Ambrobene 3 mg/ml Oral Solution	3 mg/ml	oral solution	oral use
Ireland	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Ambroxol hydrochloride	Ambrobene Extra Strength 6 mg/ml Oral Solution	6 mg/ml	oral solution	oral use
Ireland	Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom	Ambroxol hydrochloride	Lysopadol Mint 20 mg Lozenges	20 mg	lozenge	oral use
Ireland	Boehringer Ingelheim Limited Ellesfield Avenue Bracknell, Berkshire RG12 8YS United Kingdom	Ambroxol hydrochloride	Lysopadol 17,86 mg/ml Oromucosal Spray, Solution	17,86 mg/ml	oromucosal spray, solution	oromucosal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Ireland	Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom	Ambroxol hydrochloride	Lysopadol Lemon 20 mg Lozenges	20 mg	lozenge	oral use
Ireland	Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom	Ambroxol hydrochloride	Lysopadol Blackcurrant 20 mg Lozenges	20 mg	lozenge	oral use
Ireland	Boehringer Ingelheim Limited, Ellesfield Avenue Bracknell Berkshire, RG12 8YS United Kingdom	Bromohexine hydrochloride	Bisolvon 4 mg/5 ml Oral Solution	4 mg/5 ml	oral solution	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	30 mg	tablet	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan Bambini	30 mg	suppository	rectal use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	15 mg/5 ml	syrup	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	7,5 mg/ml	nebuliser solution	inhalation use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	60 mg	granules for oral solution	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	30 mg/5 ml	syrup	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Mucosolvan	15 mg	oral gum	oral use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron	15 mg/5 ml	syrup	oral use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron	0,75 %	oral solution or nebuliser solution	oral use, inhalation use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron Adulti	30 mg	granules for oral suspension	oral use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron Bambini	15 mg	granules for oral suspension	oral use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Chiesi Farmaceutici S.P.A. Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Fluibron Adulti	30 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Piam Farmaceutici S.P.A. Via Padre Semeria, 5 16131 Genova Italy	Ambroxol hydrochloride	Muciclar	15 mg/5 ml	syrup	oral use
Italy	Piam Farmaceutici S.P.A. Via Padre Semeria, 5 16131 Genova Italy	Ambroxol hydrochloride	Muciclar	75 mg	prolonged-release capsule	oral use
Italy	Piam Farmaceutici S.P.A. Via Padre Semeria, 5 16131 Genova Italy	Ambroxol hydrochloride	Muciclar	30 mg	granules for oral suspension	oral use
Italy	Piam Farmaceutici S.P.A. Via Padre Semeria, 5 16131 Genova Italy	Ambroxol hydrochloride	Muciclar	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Farmaceutici Caber S.P.A. V. Le Citta' D'europa, 681 00100 Roma Italy	Ambroxol hydrochloride	Secretil	15 mg/5 ml	syrup	oral use
Italy	Farmaceutici Caber S.P.A. V. Le Citta' D'europa, 681 00100 Roma Italy	Ambroxol hydrochloride	Secretil	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Farmaceutici Caber S.P.A. V. Le Citta' D'europa, 681 00100 Roma Italy	Ambroxol hydrochloride	Secretil	60 mg	granules for oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Farmaceutici Caber S.P.A. V. Le Citta' D'europa, 681 00100 Roma Italy	Ambroxol hydrochloride	Secretil	30 mg/4 ml	nebuliser solution	inhalation use
Italy	Abc Farmaceutici S.P.A. Corso V. Emanuele Ii, 72 10121 Torino Italy	Ambroxol hydrochloride	Ambroxolo ABC	30 mg	tablet	oral use
Italy	Abc Farmaceutici S.P.A. Corso V. Emanuele Ii, 72 10121 Torino Italy	Ambroxol hydrochloride	Ambroxolo ABC	15 mg	nebuliser solution	inhalation use
Italy	Abc Farmaceutici S.P.A. Corso V. Emanuele Ii, 72 10121 Torino Italy	Ambroxol hydrochloride	Ambroxolo ABC	30 mg	suppository	rectal use
Italy	Abc Farmaceutici S.P.A. Corso V. Emanuele Ii, 72 10121 Torino Italy	Ambroxol hydrochloride	Ambroxolo ABC	15 mg	granules for oral suspension	oral use
Italy	Abc Farmaceutici S.P.A. Corso V. Emanuele Ii, 72 10121 Torino Italy	Ambroxol hydrochloride	Ambroxolo ABC	30 mg	granules for oral suspension	oral use
Italy	Laboratorio Farmaceutico Sit Specialita' Igienico Terapeutiche S.R.L., Via Cavour, 70 Mede 27035 Pavia Italy	Ambroxol hydrochloride	Tauxolo	3 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	S.F. Group S.R.L. Via Beniamino Segre, 59 00134 Roma Italy	Ambroxol hydrochloride	Broxol	15 mg/5 ml	syrup	oral use
Italy	S.F. Group S.R.L. Via Beniamino Segre, 59 00134 Roma Italy	Ambroxol hydrochloride	Broxol Adulti	30 mg	granules	oral use
Italy	S.F. Group S.R.L. Via Beniamino Segre, 59 00134 Roma Italy	Ambroxol hydrochloride	Broxol	0,75 %	nebuliser solution	inhalation use
Italy	Actavis Group Ptc Ehf Reykjavikurvegi 76-78 220 Hafnarfjördur Iceland	Ambroxol hydrochloride	Ambroxolo Actavis	0,30 %	syrup	oral use
Italy	Istituto Chimico Internazionale Dr. Giuseppe Rende S.R.L. Via Salaria, 1240 00138 Roma Italy	Ambroxol hydrochloride	Amobronc	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Istituto Chimico Internazionale Dr. Giuseppe Rende S.R.L. Via Salaria, 1240 00138 Roma Italy	Ambroxol hydrochloride	Amobronc	15 mg/5 ml	syrup	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Surfactal	1 g/50 ml	solution for infusion	intravenous use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Farmapro S.R.L. Via Beato Sebastiano Valfre 4, 10121 Torino Italy	Ambroxol hydrochloride	Ambroxolo Pharmentis	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Ratiopharm Gmbh Graf-Arco Strasse 3 D-89079 Ulm Germany	Ambroxol hydrochloride	Ambroxolo Ratiopharm	30 mg/10 ml	syrup	oral use
Italy	Hexal S.P.A. Largo Umberto Boccioni, 1 21040 Origgio Varese Italy	Ambroxol hydrochloride	Ambroxolo Hexal	7,5 mg/ml	nebuliser solution	inhalation use
Italy	Hexal S.P.A. Largo Umberto Boccioni, 1 21040 Origgio Varese Italy	Ambroxol hydrochloride	Ambroxolo Hexal	3 mg/ml	syrup	oral use
Italy	A. Menarini Industrie Farmaceutiche Riunite S.R.L. Via Sette Santi, 3 50131 Firenze Italy	Ambroxol hydrochloride	Mucoaricodil	30 mg	tablet	oral use
Italy	A. Menarini Industrie Farmaceutiche Riunite S.R.L. Via Sette Santi, 3 50131 Firenze Italy	Ambroxol hydrochloride	Mucoaricodil	30 mg/10 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Teva Italia S.R.L. Via Messina, 38 20154 Milano Italy	Ambroxol hydrochloride	Ambroxol Dorom	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Alfa Wassermann S.P.A. Via Enrico Fermi, 1 65020 Alanno — Pescara Italy	Ambroxol hydrochloride	Lintos	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Alfa Wassermann S.P.A. Via Enrico Fermi, 1 65020 Alanno — Pescara Italy	Ambroxol hydrochloride	Lintos	30 mg/10 ml	syrup	oral use
Italy	Eg S.P.A. Via Pavia 6 20136 Milano Italy	Ambroxol hydrochloride	Ambroxolo EG	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Eg S.P.A. Via Pavia 6 20136 Milano Italy	Ambroxol hydrochloride	Ambroxolo EG	15 mg/5 ml	syrup	oral use
Italy	Eg S.P.A. Via Pavia 6 20136 Milano Italy	Ambroxol hydrochloride	Ambroxolo EG	30 mg/10 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Epifarma S.R.L Via S. Rocco, 6 85033 Episcopia -Potenza Italy	Ambroxol hydrochloride	Ambrotus	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Epifarma S.R.L Via S. Rocco, 6 85033 Episcopia -Potenza Italy	Ambroxol hydrochloride	Ambrotus	30 mg/10 ml	syrup	oral use
Italy	Farmakopea S.P.A. Via Cavriana, 14 20134 Milano Italy	Ambroxol hydrochloride	Gammaxol	15 mg/5 ml	syrup	oral use
Italy	Farmakopea S.P.A. Via Cavriana, 14 20134 Milano Italy	Ambroxol hydrochloride	Gammaxol	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Farmakopea S.P.A. Via Cavriana, 14 20134 Milano Italy	Ambroxol hydrochloride	Gammaxol	0,75 %	nebuliser solution	inhalation use
Italy	Union Health S.R.L. Via Adige, 5 66020 San Giovanni Teatino — Chieti Italy	Ambroxol hydrochloride	Ambroxol	3 mg/ml	syrup	oral use
Italy	Union Health S.R.L. Via Adige, 5 66020 San Giovanni Teatino — Chieti Italy	Ambroxol hydrochloride	Ambroxol	7,5 mg/ml	nebuliser solution	inhalation use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Union Health S.R.L. Via Adige, 5 66020 San Giovanni Teatino — Chieti Italy	Ambroxol hydrochloride	Ambroxol	0,75 %	nebuliser solution	inhalation use
Italy	Union Health S.R.L. Via Adige, 5 66020 San Giovanni Teatino — Chieti Italy	Ambroxol hydrochloride	Ambroxol	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Tecnigen S.R.L. Via Galileo Galilei 40 20092 Cinisello Balsamo — Milano Italy	Ambroxol hydrochloride	Ambroxol Tecnigen	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Tecnigen S.R.L. Via Galileo Galilei 40 20092 Cinisello Balsamo — Milano Italy	Ambroxol hydrochloride	Ambroxol Tecnigen	30 mg/10 ml	syrup	oral use
Italy	Procter & Gamble S.R.L. Viale G. Ribotta, 11 00144 Roma Italy	Ambroxol hydrochloride	Vicks tosse mucolitico	30 mg	effervescent tablet	oral use
Italy	Procter & Gamble S.R.L. Viale G. Ribotta, 11 00144 Roma Italy	Ambroxol hydrochloride	Vicks tosse mucolitico	30 mg	effervescent tablet	oral use
Italy	Almus S.R.L. Via Cesarea, 11/10 16121 Genova Italy	Ambroxol hydrochloride	Ambroxolo Almus	30 mg/10 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Almus S.R.L. Via Cesarea, 11/10 16121 Genova Italy	Ambroxol hydrochloride	Ambroxolo Almus	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Angenerico S.P.A. Via Nocera Umbra, 75 00181 Roma Italy	Ambroxol hydrochloride	Ambroxolo Angenerico	7,5 mg/ml	nebuliser solution	inhalation use
Italy	Angenerico S.P.A. Via Nocera Umbra, 75 00181 Roma Italy	Ambroxol hydrochloride	Ambroxolo Angenerico	3 mg/ml	syrup	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Ambroxol hydrochloride	Zerinol Gola menta	20 mg	tablet	oral use
Italy	Boehringer Ingelheim International Gmbh Binger Strasse 173 D55216 Ingelheim Am Rhein Germany	Ambroxol hydrochloride	Zerinol Gola ribes nero	20 mg	tablet	oral use
Italy	Wellington Street Development Pharma Limited 47, Oaklands Drive Rathgar Dublino 6 Ireland	Ambroxol hydrochloride	Brufix	0,75 %	nebuliser solution	inhalation use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Germed Pharma S.P.A. Via Cantu', 11 20092 Cinisello Balsamo — Milano Italy	Ambroxol hydrochloride	Ambroxolo Germed	15 mg/5 ml	syrup	oral use
Italy	Mylan S.P.A. Via Vittor Pisani, 20 20124 Milano Italy	Ambroxol hydrochloride	Ambroxolo Mylan Generics	15 mg/5 ml	syrup	oral use
Italy	Abc Farmaceutici S.P.A. Corso V. Emanuele Ii, 72 10121 Torino Italy	Ambroxol hydrochloride	Viscomucil	3 mg/ml	syrup	oral use
Italy	Cyathus Exquirere Pharmaforschungsgmbh Rudolfsplatz 2/1/8 1010 Vienna Austria	Ambroxol hydrochloride	Mukambro	10 mg/erogazione	oral solution	oral use
Italy	Cyathus Exquirere Pharmaforschungsgmbh Rudolfsplatz 2/1/8 1010 Vienna Austria	Ambroxol hydrochloride	Gogolox	10 mg/erogazione	oral solution	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Bromhexine hydrochloride	Bisolvon	2 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Bromhexine hydrochloride	Bisolvon	8 mg	tablet	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Bromhexine hydrochloride	Bisolvon	4 mg/2 ml	solution for injection	injection use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Bromhexine hydrochloride	Bisolvon	4 mg/5 ml	syrup	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Bromhexine hydrochloride	Bisolvon	8 mg	soluble tablet	oral use
Italy	Boehringer Ingelheim Italia S.P.A. Via Lorenzini, 8 20139 Milano Italy	Bromhexine hydrochloride	Bisolvon	8 mg/5 ml	syrup	oral use
Italy	Boots Pharmaceuticals S.R.L. Via Cesarea 11/10 16121 Genova Italy	Bromhexine hydrochloride	Nirolex tosse e catarro	4 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Aesculapius Farmaceutici Srl Via Cozzaglio, 24 25125 Brescia Italy	Bromhexine hydrochloride	Flutoxil	4 mg/5 ml	syrup	oral use
Italy	Farmapro S.R.L. Via Beato Sebastiano Valfre 4, 10121 Torino Italy	Bromhexine hydrochloride	Bromexina Pharmentis	4 mg/5 ml	syrup	oral use
Italy	Germed Pharma S.P.A. Via Cantu', 11 20092 Cinisello Balsamo — Milano Italy	Bromhexine hydrochloride	Bromexina Germed	4 mg/5 ml	syrup	oral use
Italy	Laboratorio Farmaceutico Sit Specialita' Igienico Terapeutiche S.R.L., Via Cavour, 70 Mede 27035 Pavia Italy	Bromhexine hydrochloride	Tauglicolo	40 mg	syrup	oral use
Italy	Laboratorio Farmaceutico Sit Specialita' Igienico Terapeutiche S.R.L., Via Cavour, 70 Mede 27035 Pavia Italy	Bromhexine hydrochloride	Tauglicolo Adulti	6 mg	suppository	rectal use
Italy	Laboratorio Farmaceutico Sit Specialita' Igienico Terapeutiche S.R.L., Via Cavour, 70 Mede 27035 Pavia Italy	Bromhexine hydrochloride	Tauglicolo Bambini	3 mg	suppository	rectal use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Laboratorio Farmaceutico Sit Specialita' Igienico Terapeutiche S.R.L., Via Cavour, 70 Mede 27035 Pavia Italy	Bromhexine hydrochloride/sulphuguaiacol	Tauglicolo	4 mg + 3,86 mg	solution for injection	injection use
Italy	Promedica Srl Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Ventibron	15 mg/5 ml	syrup	oral use
Italy	Promedica Srl Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Ventibron	15 mg/2 ml	nebuliser solution	inhalation use
Italy	Promedica Srl Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Ventibron	0,75 %	oral solution nebuliser solution	oral use inhalation use
Italy	Promedica Srl Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Ventibron	30 mg	tablet	oral use
Italy	Promedica Srl Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Ventibron	15 mg	granules for suspension	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Italy	Promedica Srl Via Palermo, 26/A 43122 Parma Italy	Ambroxol hydrochloride	Ventibron	30 mg	granules for suspension	oral use
Latvia	EGIS PHARMACEUTICALS PLC., 1106 BUDAPEST, Kereszturi ut 30-38, Hungary	ambroxol hydrochloride	Halixol 15 mg/5 ml syrup	15 mg/5 ml	syrup	oral use
Latvia	EGIS PHARMACEUTICALS PLC., 1106 BUDAPEST, Kereszturi ut 30-38, Hungary	ambroxol hydrochloride	Halixol 30 mg tablets	30 mg	tablet	oral use
Latvia	PRO.MED.CS Praha a.s., Telcska 1, 140 00 Praha 4, Czech Republic	ambroxol hydrochloride	Ambrosan 30 mg tablets	30 mg	tablet	oral use
Latvia	G. L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria	ambroxol hydrochloride	Ambrolan 30 mg tablets	30 mg	tablet	oral use
Latvia	STIROLBIOFARM BALTIKUM SIA, Rasas iela 5, Riga, Latvia	ambroxol hydrochloride	Ambroksols Stirol 75 mg prolonged-release tablets	75 mg	prolonged-release tablet	oral use
Latvia	BERLIN-CHEMIE AG (MENARINI GROUP), Glienicker Weg 125, 12489 Berlin, Germany	ambroxol hydrochloride	Flavamed 60 mg effervescent tablets	60 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	ratiopharm GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany	ambroxol hydrochloride	Brontex 3 mg/ml syrup	3 mg/ml	syrup	oral use
Latvia	ratiopharm GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany	ambroxol hydrochloride	Brontex 30 mg tablets	30 mg	tablet	oral use
Latvia	BERLIN-CHEMIE AG (MENARINI GROUP), Glienicker Weg 125, 12489 Berlin, Germany	ambroxol hydrochloride	Flavamed 30 mg tablets	30 mg	tablet	oral use
Latvia	BERLIN-CHEMIE AG (MENARINI GROUP), Glienicker Weg 125, 12489 Berlin, Germany	ambroxol hydrochloride	Tusmed 30 mg/5 ml oral solution	30 mg/5 ml	oral solution	oral use
Latvia	AS 'Olainfarm', Rūpnīcu iela 5, Olaine, 2114, Latvia	ambroxol hydrochloride	Ambroksol 30 mg tablets	30 mg	tablet	oral use
Latvia	Sandoz d.d., Verovskova 57, 1000 Ljubljana, Slovenia	ambroxol hydrochloride	Ambroxol Sandoz 15 mg/5 ml syrup	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	Sandoz d.d., Verovskova 57, 1000 Ljubljana, Slovenia	ambroxol hydrochloride	Ambroxol Sandoz 30 mg tablets	30 mg	tablet	oral use
Latvia	CYATHUS Exquirere Pharmaforschungs GmbH, Rudolfsplatz 2/1/8, 1010 Vienna, Austria	ambroxol hydrochloride	Mukambro 10 mg/spray puff oral solution	10 mg/spray puff	oral solution	oral use
Latvia	BERLIN-CHEMIE AG (MENARINI GROUP), Glienicker Weg 125, 12489 Berlin, Germany	ambroxol hydrochloride	Flavamed for children 15 mg/5 ml oral solution	15 mg/5 ml	oral solution	oral use
Latvia	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rein, Germany	ambroxol hydrochloride	Lasolvan 15 mg/5 ml syrup	15 mg/5 ml	syrup	oral use
Latvia	Divapharma GmbH, Motzener Str. 41, 12277 Berlin, Germany	ambroxol hydrochloride	Neo-bronchol 15 mg lozenges	15 mg	lozenge	oral use
Latvia	SIA Briz, Rasas iela 5, Riga, 1057, Latvia	ambroxol hydrochloride	Ambroxol — BCPP 30 mg tablets	30 mg	tablet	oral use
Latvia	BERLIN-CHEMIE AG (MENARINI GROUP), Glienicker Weg 125, 12489 Berlin, Germany	ambroxol hydrochloride	Flavamed 30 mg/5 ml oral solution	30 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Latvia	Actavis Nordic A/S, Ornegardsvej 16, 2820 Gentofte, Denmark	bromhexine hydrochloride	Bromhexin Actavis 8 mg tablets	8 mg	tablet	oral use
Latvia	SIA Briz, Rasas iela 5, Riga, 1057, Latvia	bromhexine hydrochloride	Bromhexin Sopharma 8 mg tablets	8 mg	tablet	oral use
Latvia	AS GRINDEKS. Krustpils, 53, Riga, 1057, Latvia	bromhexine hydrochloride	Bromhexine-Grindeks 4 mg tabletes	4 mg	tablet	oral use
Latvia	AS GRINDEKS. Krustpils, 53, Riga, 1057, Latvia	bromhexine hydrochloride	Bromhexine-Grindeks 8 mg tabletes	8 mg	tablet	oral use
Latvia	AS GRINDEKS. Krustpils, 53, Riga, 1057, Latvia	bromhexine hydrochloride	Bromhexine-Grindeks 4 mg/5 ml syrup	4 mg/5 ml	syrup	oral use
Latvia	SIA Briz, Rasas iela 5, Riga, 1057, Latvia	bromhexine hydrochloride	Bromhexin Sopharma 4 mg/5 ml syrup	4 mg/5 ml	syrup	oral use
Lithuania	CYATHUS Exquirere Pharmaforschungs GmbH Rudolfsplatz 2/1/8 1010 Vienna Austria	Ambroxol hydrochloride	AMBROSPRAY	10 mg/0,2 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Lithuania	G.L. Pharma GmbH Schlossplatz 1 8502 Lannach Austria	Ambroxol hydrochloride	Ambrolan	30 mg	tablet	oral use
Lithuania	PRO.MED.CS Praha a.s. Telčska 1140 00 Praha, Czech Republic	Ambroxol hydrochloride	Ambrosan	30 mg	tablet	oral use
Lithuania	Sandoz d.d. Verovškova 57, 1000 Ljubljana Slovenia	Ambroxol hydrochloride	Ambroxol Sandoz	30 mg	tablet	oral use
Lithuania	Sandoz d.d. Verovškova 57, 1000 Ljubljana Slovenia	Ambroxol hydrochloride	Ambroxol Sandoz	15 mg/5 ml	syrup	oral use
Lithuania	ratiopharm GmbH Graf — Arco — Str. 3 89079 Ulm, Germany	Ambroxol hydrochloride	Brontex	30 mg	tablet	oral use
Lithuania	ratiopharm GmbH Graf — Arco — Str. 3 89079 Ulm, Germany	Ambroxol hydrochloride	Brontex	7,5 mg/ml	oral drops, solution	oral use
Lithuania	ratiopharm GmbH Graf — Arco — Str. 3 89079 Ulm, Germany	Ambroxol hydrochloride	Brontex	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Lithuania	BERLIN-CHEMIE AG (MENARINI GROUP) Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	30 mg	tablet	oral use
Lithuania	BERLIN-CHEMIE AG (MENARINI GROUP) Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	60 mg	effervescent tablet	oral use
Lithuania	BERLIN-CHEMIE AG (MENARINI GROUP) Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	30 mg/5 ml	oral solution	oral use
Lithuania	BERLIN-CHEMIE AG (MENARINI GROUP) Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	15 mg/5 ml	oral solution	oral use
Lithuania	EGIS PHARMACEUTICALS PLC 1106 Budapest Keresztúri út 30-38 Hungary	Ambroxol hydrochloride	Halixol	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Lithuania	EGIS PHARMACEUTICALS PLC 1106 Budapest Keresztúri út 30-38 Hungary	Ambroxol hydrochloride	Halixol	30 mg	tablet	oral use
Lithuania	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Lasolvan	15 mg/5 ml	syrup	oral use
Lithuania	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Lasolvan	15 mg/2 ml	inhalation vapour, solution	oral use
Lithuania	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Lasolvan	30 mg	tablet	oral use
Lithuania	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Lasolvan	75 mg	prolonged-release capsule, hard	oral use
Lithuania	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Tussisol	30 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Lithuania	Divapharma GmbH Motzener Str. 41 12277 Berlin Germany	Ambroxol hydrochloride	neo-bronchol	15 mg	lozenge	oral use
Lithuania	AS GRINDEKS Krustpils 53 Rīga 1057 Latvia	Bromhexine hydrochloride	BROMHEXINE-GRINDEKS	4 mg/5 ml	syrup	oral use
Lithuania	AS GRINDEKS Krustpils 53 Rīga 1057 Latvia	Bromhexine hydrochloride	BROMHEXINE-GRINDEKS	4 mg	tablet	oral use
Lithuania	AS GRINDEKS Krustpils 53 Rīga 1057 Latvia	Bromhexine hydrochloride	BROMHEXINE-GRINDEKS	8 mg	tablet	oral use
Lithuania	Actavis Nordic A/S Ørnegårdsvej 16, 2820 Gentofte Denmark	Bromhexine hydrochloride	Bromhexin Actavis	8 mg	tablet	oral use
Lithuania	BERLIN-CHEMIE AG (MENARINI GROUP) Glienicker Weg 125 12489 Berlin Germany	Bromhexine hydrochloride	Bromhexin Berlin-Chemie	8 mg	coated tablet	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Bisolvon	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Bisolvon	8 mg/5 ml	syrup	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Bisolvon	0,20 %	oral solution	oral use
Luxembourg	Eurogenerics Heizel Esplanade b22 1020 Brussel Belgium	Bromhexine chlorhydrate	Bromhexine EG	8 mg	tablet	oral use
Luxembourg	D.J.VAN TINTELEN BEHEER B.V. Keyserwey 20 2201 CW Noordwijk Zh The Netherlands	Bromhexine chlorhydrate	Bronchi-Mereprine	8 mg	tablet	oral use
Luxembourg	Qualiphar Laboratoire Rijksweg 9 2880 Bornem Belgium	Bromhexine chlorhydrate	Toularynx Bromhexine	5 mg/5 ml	syrup	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Ambroxine	20 mg	lozenge	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Mucoangin Citron 20 mg	20 mg	lozenge	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Mucoangine Cassis	20 mg	lozenge	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Bromhexine chlorhydrate	Mucoangine Menthe	20 mg	lozenge	oral use
Luxembourg	Hexal AG Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal Hustenlöser	30 mg	tablet	oral use
Luxembourg	Hexal AG Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal Hustentropfen	7,5 mg/ml	oral drops, solution	oral use
Luxembourg	Hexal AG Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal Hustensaft für Kinder	15 mg/5 ml	oral solution	oral use
Luxembourg	Hexal AG Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambroxhexal Hustenlöser retard	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Hexal AG Industriestr. 25 83607 Holzkirchen Germany	Ambroxol hydrochloride	Ambrohexal S Brausetablette	60 mg	effervescent tablet	oral use
Luxembourg	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 30 mg Hustenlöser	30 mg	tablet	oral use
Luxembourg	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 75 mg Hustenlöser	75 mg	prolonged-release capsule, hard	oral use
Luxembourg	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm Hustensaft	15 mg/5 ml	oral solution	oral use
Luxembourg	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm Hustentropfen	7,5 mg/ml	oral drops, solution	oral use
Luxembourg	ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	Ambroxol hydrochloride	Ambroxol-ratiopharm 15 mg/2 ml Injektionslösung	15 mg/2 ml	solution for injection	intravenous use
Luxembourg	Biocodex Avenue Gallieni 7 94250 Gentilly France	Ambroxol hydrochloride	Muxol	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Biocodex Avenue Gallieni 7 94250 Gentilly France	Ambroxol hydrochloride	Muxol	3 mg/ml	oral solution	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Ambroxol hydrochloride	Surbronc	60 mg	coated tablet	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Ambroxol hydrochloride	Surbronc	30 mg/5 ml	syrup	oral use
Luxembourg	SCS Boehringer Ingelheim Comm. V. Vesalius Science Park Avenue Ariane 16 1200 Bruxelles Belgium	Ambroxol hydrochloride	Surbronc	60 mg/3 g	powder for oral solution	oral use
Malta	Medochemie Ltd. 1-10 Constantinoupoleos Street, 3011, P. O. Box 51409, 3505 Limassol, Cyprus	Ambroxol Hydrochloride	Medovent Elixir Syrup 15 mg/5 ml	15 mg/5 ml	oral solution	oral use
Malta	Mundipharma Pharmaceuticals Ltd. 13 Othellos Street, Dhali Industrial Zone, Nicosia, Cyprus	Ambroxol Hyrdochloride	Mucobroxol Syrup	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Malta	Actavis EAD 29, Atanas Dukov Street, Sofia 1407 Bulgaria	Ambroxol Hydrochloride	MUCOLISIN 30 mg/5 ml syrup	30 mg/5 ml	syrup	oral use
Malta	Aflofarm Farmacja Polska SP. zo. o. ul. Partyzancka 133/151 95-200 Pabianice, Poland	Ambroxol Hydrochloride	Entus Max 30 mg/5 ml syrup	30 mg/5 ml	syrup	oral use
Malta	PIAM Farmaceutici S.P.A. Via Padre G. Semeria, 5, I-16131, Genoa, Italy	Ambroxol Hydrochloride	Muciclar	3 mg/ml	syrup	oral use
Malta	PIAM Farmaceutici S.P.A. Via Padre G. Semeria, 5, I-16131, Genoa, Italy	Ambroxol Hydrochloride	Muciclar	75 mg	modified release capsule	oral use
Malta	Boehringer Ingelheim Ellas A.E. Ellinikou 2, 167 77 Elliniko, Athens, Greece	Ambroxol Hydrochloride (Cyclohexanol Hydrochloride)	Mucosolvan	15 mg/5 ml	syrup	oral use
Malta	Boehringer Ingelheim Ellas A.E. Ellinikou 2, 167 77 Elliniko, Athens, Greece	Ambroxol Hydrochloride (Cyclohexanol Hydrochloride)	Mucosolvan	30 mg	tablet	oral use
Malta	Sopharma PLC 16, Iliensko Shosse Str. 1220 Sofia, Bulgaria	Bromhexine hydrochloride	BROMHEXINE SOPHARMA 4 mg/5 ml syrup	4 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Malta	Adelco-Chromatourgia Anthinon E. Colocotronis Bros S.A. 37 Pireos Str, 183 46, Moschato, Athens, Greece	Bromhexine Hydrochloride	Bronchotussine	4 mg/5 ml	syrup	oral use
Malta	Boehringer Ingelheim Limited Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom	Bromhexine Hydrochloride	Bisolvon 4 mg/5 ml Oral Solution	4 mg/5 ml	oral solution	oral use
Malta	Remedica Ltd. Limassol Industrial Estate, Aharnon Street, P.O. Box 51706, 3508 Limassol, Cyprus	Bromhexine Hydrochloride BP	Flecoxin 8 Tablets	8 mg	tablet	oral use
Norway	AS Den norske Eterfabrikk, Karihaugveien 22, 1086 Oslo, Norway	Bromhexine hydrochloride	Bromhexine DnE	1,6 mg/ml	oral solution	oral use
Norway	AS Den norske Eterfabrikk, Karihaugveien 22, 1086 Oslo, Norway	Bromhexine hydrochloride	Bromhexine DnE	0,8 mg/ml	oral solution	oral use
Norway	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55 216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	0,8 mg/ml	oral solution	oral use
Norway	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55 216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	1,6 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Norway	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55 216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	0,8 mg/ml	oral solution	oral use
Norway	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55 216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	1,6 mg/ml	oral solution	oral use
Norway	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55 216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	8 mg	tablet	oral use
Norway	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55 216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	8 mg	soluble tablet	oral use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c Praha 7 Holesovice, 170 00 Czech Republic	Ambroxol hydrochloride	Aflegan	7,5 mg/ml	solution for injection	intravenous use
Poland	Sandoz GmbH Biochemiestrasse 10 6250 Kundl Austria	Ambroxol hydrochloride	Ambrohexal	7,5 mg/ml	solution for injection	intravenous use, intramuscular use, subcutaneous use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Takeda Pharma Sp. z o.o. Al. Jerozolimskie 146 A 02-305 Warszawa Poland	Ambroxol hydrochloride	Ambroksol Takeda	15 mg/5 ml	syrup	oral use
Poland	Takeda Pharma Sp. z o.o. Al. Jerozolimskie 146 A 02-305 Warszawa Poland	Ambroxol hydrochloride	Ambroksol Takeda	30 mg/5 ml	syrup	oral use
Poland	PRO.MED.CS. Praha a.s. Telcska 1 Praha 4 140 00 Czech Republic	Ambroxol hydrochloride	Ambrosan	30 mg	tablet	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambrosol Teva	15 mg/5 ml	syrup	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambrosol Teva	30 mg	tablet	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambrosol Teva	30 mg/5 ml	syrup	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambrosolvan	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambrosolvan	30 mg/5 ml	syrup	oral use
Poland	Sopharma Warszawa Sp. z o.o. ul. Ostrobramska 91 04-118 Warszawa Poland	Ambroxol hydrochloride	Ambrotaxer	15 mg/5 ml	syrup	oral use
Poland	123ratio Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambroxol 123ratio	3 mg/ml	oral solution	oral use
Poland	123ratio Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Ambroxol hydrochloride	Ambroxol 123ratio	6 mg/ml	oral solution	oral use
Poland	Cyathus Exquirere Pharmaforschungs GmbH Rudolfsplatz 2/1/8 1010 Wienn Austria	Ambroxol hydrochloride	Ambroxol hydrochloride Cyathus	10 mg/dawkę	oral solution	oral use
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Ambroxoli hydrochloridum Fontane	15 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c Praha 7 Holesovice, 170 00 Czech Republic	Ambroxol hydrochloride	Deflegmin	7,5 mg/ml	oral drops, solution	oral use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c Praha 7 Holesovice 17000 Czech Republic	Ambroxol hydrochloride	Deflegmin	30 mg	tablet	oral use
Poland	ICN Polfa Rzeszów S.A. ul. Przemysłowa 2 35-959 Rzeszów Poland	Ambroxol hydrochloride	Deflegmin	30 mg/5 ml	syrup	oral use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c Praha 7 Holesovice, 17000 Czech Republic	Ambroxol hydrochloride	Deflegmin	75 mg	prolonged-release capsule	oral use
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c Praha 7 Holesovice, 17000 Czech Republic	Ambroxol hydrochloride	Deflegmin	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	PharmaSwiss Ceska Republika s.r.o. Jankovcova 1569/2c Praha 7 Holesovice, 17000 Czech Republic	Ambroxol hydrochloride	Deflegmin	10 mg/ml	oral solution	oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Ambroxol hydrochloride	Entus Junior	15 mg/5 ml	syrup	oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Ambroxol hydrochloride	Entus Max	30 mg/5 ml	syrup	oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Ambroxol hydrochloride	Envil kaszel	30 mg/5 ml	syrup	oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Ambroxol hydrochloride	Envil kaszel	30 mg	tablet	oral use
Poland	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice Poland	Ambroxol hydrochloride	Envil kaszel junior	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	15 mg/5 ml	syrup	oral use
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	30 mg	tablet	oral use
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed	60 mg	effervescent tablet	oral use
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Ambroxol hydrochloride	Flavamed max	30 mg/5 ml	oral solution	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Wsrszawa Poland	Bromhexine hydrochloride	Flegamina	8 mg	tablet	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Wsrszawa Poland	Bromhexine hydrochloride	Flegamina Baby	2 mg/ml	oral drops, solution	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Wsrszawa Poland	Bromhexine hydrochloride	Flegamina o smaku malinowym	4 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Wsrszawa Poland	Bromhexine hydrochloride	Flegamina o smaku miętowym	4 mg/5 ml	syrup	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Wsrszawa Poland	Bromhexine hydrochloride	Flegamina o smaku miętowym bez cukru	4 mg/5 ml	syrup	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Wsrszawa Poland	Bromhexine hydrochloride	Flegamina o smaku truskawkowym	2 mg/5 ml	syrup	oral use
Poland	Herbapol — Lublin S.A. ul. Diamentowa 25 20-471 Lublin Poland	Bromhexine hydrochloride Extractum fluidum aquosum ex Plantaginis lanceolatae folii et Verbasci floribus	Flegatussin	(0,0026 g + 2,35 g)/ 5 ml	syrup	oral use
Poland	Zentiva, k.s. U kabelovny 130 Praga 10, 10237 Dolni Mecholupy Czech Republic	Ambroxol hydrochloride	MEDOX	15 mg/5 ml	syrup	oral use
Poland	Zentiva, k.s. U kabelovny 130 Praga 10, 10237 Dolni Mecholupy Czech Republic	Ambroxol hydrochloride	Medox	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucoangin	20 mg	chewable tablet	oral use
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	30 mg/5 ml	syrup	oral use
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	30 mg	tablet	oral use
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	30 mg/5 ml	syrup	oral use
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan	15 mg	pastille	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan inhalacje	15 mg/2 ml	nebuliser liquid	inhalation use
Poland	Boehringer Ingelheim International GmbH Binger Str 173 55216 Ingelheim am Rhein Germany	Ambroxol hydrochloride	Mucosolvan mini	15 mg/5 ml	syrup	oral use
Poland	Biofarm Sp. z o.o. ul. Wałbrzyska 13 60-198 Poznań Poland	Ambroxol hydrochloride	Tussal Expectorans	30 mg	tablet	oral use
Portugal	Laboratórios Azevedos — Indústria Farmacêutica, S.A. Edifícios Azevedos — Estrada Nacional 117-2, Alfragide 2614-503 Amadora Portugal	Ambroxol	Ambroxol Tussilene	6 mg/ml	syrup	oral use
Portugal	Cinfa Portugal, Lda. Av. Tomás Ribeiro, 43 — Bloco 2, 3º F — Edifício Neopark 2790-221 Carnaxide Portugal	Ambroxol	Ambroxol Cinfa 3 mg/ml Xarope	3 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra Portugal	Ambroxol	Ambroxol Farmoz 15 mg/5 ml Xarope	3 mg/ml	syrup	oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra Portugal	Ambroxol	Ambroxol Farmoz 30 mg Comprimidos	30 mg	tablet	oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra Portugal	Ambroxol	Ambroxol Farmoz 30 mg/5 ml Xarope	6 mg/ml	syrup	oral use
Portugal	Baldacci — Portugal, S.A. Rua Cândido de Figueiredo, 84-B 1549-005 Lisboa Portugal	Ambroxol	Ambroxol Fluidox 30 mg Comprimidos	30 mg	tablet	oral use
Portugal	Baldacci — Portugal, S.A. Rua Cândido de Figueiredo, 84-B 1549-005 Lisboa Portugal	Ambroxol	Ambroxol Fluidox 6 mg/ml Xarope	6 mg/ml	syrup	oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Ambroxol	Ambroxol Generis 3 mg/ml Xarope	3 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 — 1º Dto — Edifício Monsanto 2790-012 Portela de Carnaxide Portugal	Ambroxol	Ambroxol Germed 3 mg/ml Xarope	3 mg/ml	syrup	oral use
Portugal	Germed Farmacêutica, Lda. Rua Alto do Montijo, 13 — 1º Dto — Edifício Monsanto 2790-012 Portela de Carnaxide Portugal	Ambroxol	Ambroxol Germed 6 mg/ml Xarope	6 mg/ml	syrup	oral use
Portugal	Ratiopharm — Comércio e Indústria de Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 5 A, Piso 2 2740-245 Porto Salvo Portugal	Ambroxol	Ambroxol Ratiopharm	6 mg/ml	oral solution	oral use
Portugal	Ratiopharm — Comércio e Indústria de Produtos Farmacêuticos, Lda. Lagoas Park, Edifício 5 A, Piso 2 2740-245 Porto Salvo Portugal	Ambroxol	Ambroxol Ratiopharm	3 mg/ml	oral solution	oral use
Portugal	Sandoz Farmacêutica, Lda. Avenida Professor Doutor Cavaco Silva, 10E — Taguspark 2740-255 Porto Salvo Portugal	Ambroxol	Ambroxol Sandoz	6 mg/ml	syrup	oral use
Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 — Vala do Carregado 2600-726 Castanheira do Ribatejo Portugal	Ambroxol	Benflux	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 — Vala do Carregado 2600-726 Castanheira do Ribatejo Portugal	Ambroxol	Benflux	3 mg/ml	syrup	oral use
Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 — Vala do Carregado 2600-726 Castanheira do Ribatejo Portugal	Ambroxol	Benflux Forte	6 mg/ml	syrup	oral use
Portugal	Farma 1000 — Prod. Farmacêuticos, Lda. Avenida Mestre Cid, 8 — 1º Esq. Frente 2070-012 Cartaxo Portugal	Ambroxol	Bromax	120 mg	prolonged-release capsule, hard	oral use
Portugal	Farma 1000 — Prod. Farmacêuticos, Lda. Avenida Mestre Cid, 8 — 1º Esq. Frente 2070-012 Cartaxo Portugal	Ambroxol	Bromax	30 mg	tablet	oral use
Portugal	Farma 1000 — Prod. Farmacêuticos, Lda. Avenida Mestre Cid, 8 — 1º Esq. Frente 2070-012 Cartaxo Portugal	Ambroxol	Bromax	6 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol	Broncoliber	30 mg	tablet	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol	Broncoliber	3 mg/ml	syrup	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol	Broncoliber	6 mg/ml	syrup	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol	Broncoliber	120 mg	prolonged-release capsule, hard	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol	Broncoliber	50 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Basi — Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Ambroxol	Broncosil	6 mg/ml	syrup	oral use
Portugal	Labialfarma — Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A. Edifício Labialfarma, 1 — Felgueira 3450-336 Sobral — Mortágua Portugal	Ambroxol	Bronxol	30 mg	tablet	oral use
Portugal	Labialfarma — Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A. Edifício Labialfarma, 1 — Felgueira 3450-336 Sobral — Mortágua Portugal	Ambroxol	Bronxol	6 mg/ml	syrup	oral use
Portugal	Pentafarma — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Clembroxol	3 mg/ml + 0,002 mg/ml	syrup	oral use
Portugal	Pentafarma — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Clembroxol	30 mg + 0,02 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Pentafarma — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Clembroxol	1,5 mg/ml + 0,001 mg/ml	syrup	oral use
Portugal	Pentafarma — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Clembroxol	30 mg + 0,02 mg	granules	oral use
Portugal	Laboratórios Vitória, S.A. Rua Elias Garcia, 28 — Venda Nova 2700-327 Amadora Portugal	Ambroxol	Drenoxol	30 mg	tablet	oral use
Portugal	Laboratórios Vitória, S.A. Rua Elias Garcia, 28 — Venda Nova 2700-327 Amadora Portugal	Ambroxol	Drenoxol	30 mg/10 ml	syrup	oral use
Portugal	Laboratórios Vitória, S.A. Rua Elias Garcia, 28 — Venda Nova 2700-327 Amadora Portugal	Ambroxol	Drenoxol	3 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Sofex Farmacêutica, Lda. Rua Sebastião e Silva, 25 2745-838 Massamá Portugal	Ambroxol	Fluidrenol	6 mg/ml	syrup	oral use
Portugal	Sofex Farmacêutica, Lda. Rua Sebastião e Silva, 25 2745-838 Massamá Portugal	Ambroxol	Fluidrenol	30 mg	tablet	oral use
Portugal	Distrifarma — Companhia de Distribuição Farmacêutica, S.A. Estrada Consiglieri Pedroso, 80 — Lt. 3 — Armz. 1/12 — Queluz de Baixo 2745-553 Barcarena Portugal	Ambroxol	Lactucol	6 mg/ml	syrup	oral use
Portugal	Medinfar Consumer Health — Produtos Farmacêuticos, Lda. Rua Henrique Paiva Couceiro, 27 — Venda Nova 2700-451 Amadora Portugal	Ambroxol	Mucodrenol	6 mg/ml	syrup	oral use
Portugal	Medinfar Consumer Health — Produtos Farmacêuticos, Lda. Rua Henrique Paiva Couceiro, 27 — Venda Nova 2700-451 Amadora Portugal	Ambroxol	Mucodrenol	30 mg/5 ml	syrup	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol	Mucosolvan	15 mg/2 ml	solution for injection	intravenous use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol	Mucosolvan	30 mg/5 ml	syrup	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol	Mucosolvan	6 mg/ml	syrup	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol	Mucosolvan	15 mg	pastille	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol	Mucosolvan	30 mg	tablet	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol	Mucosolvan Perlonguets	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol + Clenbuterol	Mucospas	3 mg/ml + 0,002 mg/ml	syrup	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Ambroxol + Clenbuterol	Mucospas	1,5 mg/ml + 0,001 mg/ml	syrup	oral use
Portugal	Labialfarma — Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A. Edifício Labialfarma, 1 — Felgueira 3450-336 Sobral — Mortágua Portugal	Ambroxol	Mucotosse	6 mg/ml	syrup	oral use
Portugal	Labialfarma — Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A. Edifício Labialfarma, 1 — Felgueira 3450-336 Sobral — Mortágua Portugal	Ambroxol	Mucotosse	30 mg	tablet	oral use
Portugal	Sociedade Farmacêutica Gestafarma, Lda. Rua Aquilino Ribeiro, 6-A 2790-027 Carnaxide Portugal	Ambroxol	Spectorum Expectorante	6 mg/ml	syrup	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Ventoliber	1,5 mg/ml + 0,001 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Ventoliber	3 mg/ml + 0,002 mg/ml	syrup	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Ventoliber	30 mg + 0,02 mg	granules	oral use
Portugal	Tecnimede — Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 — Abrunheira 2710-089 Sintra Portugal	Ambroxol + Clenbuterol	Ventoliber	30 mg + 0,02 mg	tablet	oral use
Portugal	Laboratórios Basi — Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Bromhexine	Basiflux	0,8 mg/ml	syrup	oral use
Portugal	Laboratórios Basi — Indústria Farmacêutica, S.A Parque Industrial Manuel Lourenço Ferreira, Lote 15 3450-232 Mortágua Portugal	Bromhexine	Basiflux	1,6 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Bromhexine	Bisolvon	8 mg	tablet	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Bromhexine	Bisolvon	8 mg/5 ml	syrup	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Bromhexine	Bisolvon	8 mg	dispersible tablet	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Bromhexine	Bisolvon	2 mg/ml	oral solution	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Bromhexine	Bisolvon Linctus Adulto	1,6 mg/ml	syrup	oral use
Portugal	Unilfarma — União Internacional Laboratórios Farmacêuticos, Lda. Avenida de Pádua, 11 1800-294 Lisboa Portugal	Bromhexine	Bisolvon Linctus Criança	0,8 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Azevedos — Indústria Farmacêutica, S.A. Edifícios Azevedos — Estrada Nacional 117-2, Alfragide 2614-503 Amadora Portugal	Bromhexine	Bromexina Tussilene	0,8 mg/ml	syrup	oral use
Portugal	Bluepharma Genéricos — Comércio de Medicamentos, S.A. São Martinho do Bispo 3045-016 Coimbra Portugal	Bromhexine	Bromexina Bluepharma	1,6 mg/ml	syrup	oral use
Portugal	Bluepharma Genéricos — Comércio de Medicamentos, S.A. São Martinho do Bispo 3045-016 Coimbra Portugal	Bromhexine	Bromexina Bluepharma	0,8 mg/ml	syrup	oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra Portugal	Bromhexine	Bromexina Farmoz	1,6 mg/ml	syrup	oral use
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2, Abrunheira 2710-089 Sintra Portugal	Bromhexine	Bromexina Farmoz	0,8 mg/ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Bromhexine	Bromexina Generis	0,8 mg/ml	syrup	oral use
Portugal	Generis Farmacêutica, S.A. Rua João de Deus, 19 2700-487 Amadora Portugal	Bromhexine	Bromexina Generis	1,6 mg/ml	syrup	oral use
Portugal	Labialfarma — Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A. Edifício Labialfarma, 1 — Felgueira 3450-336 Sobral — Mortágua Portugal	Bromhexine	Bromexina Wynn	1,6 mg/ml	syrup	oral use
Portugal	Labialfarma — Laboratório de Produtos Farmacêuticos e Nutracêuticos, S.A. Edifício Labialfarma, 1 — Felgueira 3450-336 Sobral — Mortágua Portugal	Bromhexine	Bromexina Wynn	0,8 mg/ml	syrup	oral use
Portugal	Caldeira & Metelo, Lda. Estrada de Paço de Arcos, 88 — Cacém Park, Armazém 27 2735-307 Agualva-Cacém Portugal	Bromhexine	Bromocal	0,8 mg/ml	syrup	oral use
Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 — Vala do Carregado 2600-726 Castanheira do Ribatejo Portugal	Bromhexine	Lisomucin	2 mg/ml	oral drops, solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Atral, S.A. Rua da Estação, 42 — Vala do Carregado 2600-726 Castanheira do Ribatejo Portugal	Bromhexine	Lisomucin	1,6 mg/ml	syrup	oral use
Portugal	Medinfar Consumer Health — Produtos Farmacêuticos, Lda. Rua Henrique Paiva Couceiro, 27 — Venda Nova 2700-451 Amadora Portugal	Bromhexine	Tosseque	0,8 mg/ml	syrup	oral use
Romania	BOEHRINGER INGELHEIM INTERNATIONAL GmbH Binger Strasse 173, D-55 216 Ingelheim am Rhein, Germany	ambroxol hydrochloride	MUCOSOLVAN JUNIOR 15 mg/5 ml	15 mg/5 ml	syrup	oral use
Romania	BOEHRINGER INGELHEIM INTERNATIONAL GmbH Binger Strasse 173, D-55 216 Ingelheim am Rhein, Germany	ambroxol hydrochloride	MUCOSOLVAN 30 mg/5 ml	30 mg/5 ml	syrup	oral use
Romania	BOEHRINGER INGELHEIM INTERNATIONAL GmbH Binger Strasse 173, D-55 216 Ingelheim am Rhein, Germany	ambroxol hydrochloride	MUCOSOLVAN 30 mg	30 mg	tablet	oral use
Romania	BOEHRINGER INGELHEIM INTERNATIONAL GmbH Binger Strasse 173, D-55 216 Ingelheim am Rhein, Germany	ambroxol hydrochloride	MUCOSOLVAN MAX	75 mg	prolonged-release capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	BOEHRINGER INGELHEIM INTERNATIONAL GmbH Binger Strasse 173, D-55 216 Ingelheim am Rhein, Germany	ambroxol hydrochloride	MUCOSOLVAN 15 mg gumă orală	15 mg	oral gum	oral use
Romania	ALIUD PHARMA GmbH & Co. KG Gottlieb-Daimler-Straβe 19, 89150 Laichingen, Germany	ambroxol hydrochloride	AMBROXOL AL 15 mg/5 ml	15 mg/5 ml	syrup	oral use
Romania	ALIUD PHARMA GmbH & Co. KG Gottlieb-Daimler-Straβe 19, 89150 Laichingen, Germany	ambroxol hydrochloride	AMBROXOL AL 7,5 mg/ml	7,5 mg/ml	oral drops, solution	oral use
Romania	ALIUD PHARMA GmbH & Co. KG Gottlieb-Daimler-Straβe 19, 89150 Laichingen, Germany	ambroxol hydrochloride	AMBROXOL AL 30 mg	30 mg	tablet	oral use
Romania	S.C. ARENA GROUP S.A. Str. Ştefan Mihăileanu nr. 31, Sector 2, Bucureşti, cod postal 024022, Romania	ambroxol hydrochloride	AMBROXOL ARENA 30 mg	30 mg	tablet	oral use
Romania	Zentiva, k.s. U kabelovny 130 Dolni Měcholupy 102 37 Praha 10 Czech Republic	ambroxol hydrochloride	MUCOSIN CU MIERE sirop, 15 mg/5 ml	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	Zentiva, a.s. Einsteinova 24 851 01, Bratislava Slovak Republic	ambroxol hydrochloride	MUCOSIN 30 mg comprimate	30 mg	tablet	oral use
Romania	HEXAL AG, Industriestrasse 25, D-83607 Holzkirchen, Germany	ambroxol hydrochloride	AMBROXOL SANDOZ comprimate, 30 mg	30 mg	tablet	oral use
Romania	HEXAL AG, Industriestrasse 25, D-83607 Holzkirchen, Germany	ambroxol hydrochloride	AMBROXOL SANDOZ SIROP	3 mg/ml	syrup	oral use
Romania	BERLIN-CHEMIE AG (Menarini Group) Glienicker Weg 125 D-12489 Berlin, Germany	ambroxol hydrochloride	FLAVAMED 60 mg	60 mg	effervescent tablet	oral use
Romania	BERLIN-CHEMIE AG (Menarini Group) Glienicker Weg 125 D-12489 Berlin, Germany	ambroxol hydrochloride	FLAVAMED 30 mg	30 mg	tablet	oral use
Romania	BERLIN-CHEMIE AG (Menarini Group) Glienicker Weg 125 D-12489 Berlin, Germany	ambroxol hydrochloride	FLAVAMED 30 mg/5 ml soluție orală	30 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	BERLIN-CHEMIE AG (Menarini Group) Glienicker Weg 125 D-12489 Berlin, Germany	ambroxol hydrochloride	FLAVAMED 15 mg/5 ml	15 mg/5 ml	oral solution	oral use
Romania	VIM SPECTRUM SRL, ROMANIA Şos. Sighişoarei nr. 409, Târgu Mureş (Corunca), Romania	ambroxol hydrochloride	AMBROXOL 30 mg	30 mg	tablet	oral use
Romania	Egis Pharmaceuticals Plc Kereszturi ut 30-38 Budapest H-1106 Hungary	ambroxol hydrochloride	AMBROXOL EGIS sirop, 3 mg/ml	3 mg/ml	syrup	oral use
Romania	Egis Pharmaceuticals Plc Kereszturi ut 30-38 Budapest H-1106 Hungary	ambroxol hydrochloride	AMBROXOL EGIS, comprimate, 30 mg	30 mg	tablet	oral use
Romania	GEDEON RICHTER ROMÂNIA S.A., ROMANIA Str. Cuza-Vodă nr. 99-105, Târgu Mureş, Romania	ambroxol hydrochloride	AMBROXOL 30 mg/5 ml	30 mg/5 ml	syrup	oral use
Romania	GEDEON RICHTER ROMÂNIA S.A., ROMANIA Str. Cuza-Vodă nr. 99-105, Târgu Mureş, Romania	ambroxol hydrochloride	AMBROXOL RICHTER 30 mg	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	TIS FARMACEUTIC SA, Sos. Industriilor nr. 16 Sector 3, Bucuresti, Romania	ambroxol hydrochloride	AMBROXOL 0,3 % soluție orală	0,30 %	oral solution	oral use
Romania	TIS FARMACEUTIC SA, Sos. Industriilor nr. 16 Sector 3, Bucuresti, Romania	ambroxol hydrochloride	AMBROXOL 0,75 % picaturi orale soluție	0,75 %	oral drops, solution	oral use
Romania	CYATHUS EXQUIRERE Pharmaforschungs GmbH Rudolfsplatz 2/1/8 A-1010 Viena, Austria	ambroxol hydrochloride	AMBROSPRAY	10 mg/pulverizare	oromucosal spray	oral use
Romania	BIOFARM S.A., Str.Logofat Tautu Nr. 99 Sector 3, Bucureşti 031212 Romania	ambroxol hydrochloride	AMBROXOL BIOFARM 15 mg/5 ml, sirop	15 mg/5 ml	syrup	oral use
Romania	Farmaceutica REMEDIA S.A. Blv. Metalurgiei nr. 78, sector 4, 041836 Bucureşti, Romania	ambroxol hydrochloride	Neo-bronchol 15 mg pastile	15 mg	lozenge	oral use
Romania	ROMPHARM COMPANY SRL, Str. Eroilor, 1A, Otopeni, Romania	ambroxol hydrochloride	AMBROXOL ROMPHARM 15 mg/5 ml, sirop	15 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	LAROPHARM SRL, Sos. Alexandriei 145 A, B07 Bragadiru, Judetul Ilfov, Romania	ambroxol hydrochloride	AMBROXOL LAROPHARM 30 mg, comprimate	30 mg	tablet	oral use
Romania	LAROPHARM SRL, Sos. Alexandriei 145 A, B07 Bragadiru, Judetul Ilfov, Romania	ambroxol hydrochloride	AMBROXOL LAROPHARM 15 mg/5 ml soluție orală	15 mg/5 ml	oral solution	oral use
Romania	SOLACIUM PHARMA S.R.L., str. Calea Rahovei nr. 266-268, corp. 60, axele A-B, stalpii 11-16, etaj II, birou 1, sector 5, Bucuresti Romania	bromhexine hydrochloride	BROMHEXIN SOLACIUM 8 mg	8 mg	tablet	oral use
Romania	LAROPHARM SRL, Sos. Alexandriei 145 A, B07 Bragadiru, Judetul Ilfov, Romania	bromhexine hydrochloride	BRONHOSOLV 10 mg/5 ml	10 mg/5 ml	oral solution	oral use
Romania	LABORMED PHARMA S.A. Adresa: Bd. Theodor Pallady nr. 44B, sector 3, Bucuresti 032266 Romania	bromhexine hydrochloride	BROMHEXIN LABORMED 8 mg	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	MAGISTRA C & C, Bd. Aurel Vlaicu nr. 82A, 900055 Constanta, Romania	bromhexine hydrochloride	BROMHEXIN® 8 mg	8 mg	tablet	oral use
Romania	LAROPHARM SRL, Sos. Alexandriei 145 A, B07 Bragadiru, Judetul Ilfov, Romania	bromhexine hydrochloride	BRONHOSOLV	8 mg	tablet	oral use
Romania	TIS FARMACEUTIC SA, Sos. Industriilor nr. 16 Sector 3, Bucuresti, Romania	bromhexine hydrochloride	BROMHEXIN — T	2 mg/ml	oral drops, solution	oral use
Romania	BIO EEL SRL, str. Bega nr. 4, Targu-Mures, 540390, Romania	bromhexine hydrochloride	BROMFLUEX 8 mg	8 mg	tablet	oral use
Romania	BIO EEL SRL, str. Bega nr. 4, Targu-Mures, 540390, Romania	bromhexine hydrochloride	BROMFLUEX 12 mg	12 mg	tablet	oral use
Romania	A.C. HELCOR PHARMA SRL, str. Dr. Victor Babeş nr. 50, Baia Mare, Maramureş, Romania	bromhexine hydrochloride	BROMHEXIN HELCOR 8 mg	8 mg	tablet	oral use
Romania	ARENA GROUP SA, Bucuresti, str. Stefan Mihaileanu, nr. 31, sector 2, Romania	bromhexine hydrochloride	BROMHEXIN ARENA 8 mg	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	ARENA GROUP SA, Bucuresti, str. Stefan Mihaileanu, nr. 31, sector 2, Romania	bromhexine hydrochloride	BROMHEXIN ARENA 12 mg	12 mg	tablet	oral use
Romania	LAROPHARM SRL, Sos. Alexandriei 145 A, B07 Bragadiru, Judetul Ilfov, Romania	bromhexine hydrochloride	BROMHEXIN LAROPHARM 12 mg	12 mg	tablet	oral use
Romania	ROMPHARM COMPANY SRL, Str. Eroilor, 1A, Otopeni, Romania	bromhexine hydrochloride	BROMHEXIN ROMPHARM 2 mg/ml	2 mg/ml	oral drops, solution	oral use
Romania	SLAVIA PHARM SRL, Bd. Pallady Theodor, 44C, Bucuresti-Sector 3, 021 304 6385, Romania	bromhexine hydrochloride	ROMHEXIN SLAVIA 8 mg	8 mg	tablet	oral use
Romania	FARMACOM S.A., str. Zizinului nr. 112, 500407, Brasov, Romania	bromhexine hydrochloride	BROMHEXIN FARMACOM 8 mg	8 mg	tablet	oral use
Romania	ANTIBIOTICE SA Str. Valea Lupului nr. 1, Iasi 707410, Romania	bromhexine hydrochloride	BROMHEXIN ATB 8 mg	8 mg	tablet	oral use
Romania	BIOFARM S.A., Str.Logofat Tautu Nr. 99 Sector 3 031212 Romania	bromhexine hydrochloride	BROMHEXIN BIOFARM 8 mg	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Romania	BIOFARM S.A., Str.Logofat Tautu Nr. 99 Sector 3 031212 Romania	bromhexine hydrochloride	BROMHEXIN BIOFARM 12 mg	12 mg	tablet	oral use
Slovak Republic	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 15 mg	15 mg/2 ml	solution for injection	intravenous use
Slovak Republic	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 15 mg/5 ml	15 mg/5 ml	syrup	oral use
Slovak Republic	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 30 mg	30 mg	tablet	oral use
Slovak Republic	TEVA Pharmaceuticals Slovakia, s.r.o. Teslova 26 821 02 Bratislava Slovak Republic	ambroxol hydrochloride	Ambrobene 6 mg/ml oral solution	6 mg/1 ml	oral solution	oral use
Slovak Republic	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene 7,5 mg/ml	7,5 mg/ml	oral/inhalation solution	oral use, inhalation use
Slovak Republic	ratiopharm GmbH Graf-Arco-Str. 3 89079 Ulm Germany	ambroxol hydrochloride	Ambrobene retard 75 mg	75 mg	prolonged-release capsule	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Praha 4 Czech Republic	ambroxol hydrochloride	AMBROSAN 15 mg/5 ml sirup	15 mg/5 ml	syrup	oral use
Slovak Republic	PRO.MED.CS Praha a.s. Telčská 1 140 00 Praha 4 Czech Republic	ambroxol hydrochloride	Ambrosan 30 mg	30 mg	tablet	oral use
Slovak Republic	ALIUD PHARMA GmbH Gottlieb-Daimler-Straße 19, 89150 Laichingen Germany	ambroxol hydrochloride	Ambroxol AL 75 retard	75 mg	prolonged-release capsule	oral use
Slovak Republic	ALIUD PHARMA GmbH Gottlieb-Daimler-Straße 19, 89150 Laichingen Germany	ambroxol hydrochloride	AMBROXOL AL KVAPKY	7,5 mg/1 ml	oral drops	oral use
Slovak Republic	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed 15 mg/5 ml perorálny roztok	3 mg/1 ml	oral solution	oral use
Slovak Republic	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed Cough Tablets	30 mg	tablet	oral use
Slovak Republic	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed forte perorálny roztok	6 mg/1 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed šumivé tablety	60 mg	effervescent tablet	oral use
Slovak Republic	CYATHUS EXQUIRERE Pharmaforschungs GmbH Rudolfsplatz 2/1/8 1010 Wien Austria	ambroxol hydrochloride	GOGOLOX	50 mg/1 g	oral solution	oral use
Slovak Republic	EGIS Pharmaceuticals PLC Keresztúri út 30-38. 1106 Budapest Hungary	ambroxol hydrochloride	Halixol 30 mg	30 mg	tablet	oral use
Slovak Republic	Zentiva, k.s. U Kabelovny 130 102 37 Praha 10 Czech Republic	ambroxol hydrochloride	MUCOSIN s medom sir	15 mg/5 ml	syrup	oral use
Slovak Republic	Zentiva, a.s. Einsteinova 24 851 01, Bratislava Slovak Republic	ambroxol hydrochloride	MUCOSIN tablety	30 mg	tablet	oral use
Slovak Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan	15 mg	pastille	oral use
Slovak Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan	30 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan Junior	3 mg/1 ml	syrup	oral use
Slovak Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan Retard	75 mg	prolonged-release capsule	oral use
Slovak Republic	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany	ambroxol hydrochloride	Mucosolvan Tablety	30 mg	tablet	oral use
Slovak Republic	Divapharma GmbH Motzener Straße 41 12277 Berlin Germany	ambroxol hydrochloride	neo-bronchol	15 mg	pastille	oral use
Slovak Republic	KRKA, d.d. Šmarješka cesta 6 8000 Novo mesto Slovenia	ambroxol hydrochloride	Solvolan	30 mg	tablet	oral use
Slovak Republic	KRKA, d.d. Šmarješka cesta 6 8000 Novo mesto Slovenia	ambroxol hydrochloride	Solvolan	15 mg/5 ml	syrup	oral use
Slovak Republic	WALMARK, a.s. Oldřichovice 44 739 61 Třinec Czech Republic	ambroxol hydrochloride	Stopex na vykašliavanie	60 mg	effervescent tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	bromhexine hydrochloride	Bromhexin 12 BC	12 mg/1 ml	oral solution	oral use
Slovak Republic	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	bromhexine hydrochloride	Bromhexin 8 Berlin-Chemie	8 mg	film-coated tablet	oral use
Slovak Republic	Krewel Meuselbach GmbH Krewelstraße 2 53783 Eitorf Germany	bromhexine hydrochloride	BROMHEXIN 12 KVAPKY KM	12 mg/1 ml	oral drops	oral use
Slovak Republic	Krewel Meuselbach GmbH Krewelstraße 2 53783 Eitorf Germany	bromhexine hydrochloride	Bromhexin 8 sirup KM	8 mg/10 ml	syrup	oral use
Slovak Republic	Krewel Meuselbach GmbH Krewelstraße 2 53783 Eitorf Germany	bromhexine hydrochloride	Bromhexin 8-kvapky KM	8 mg/ml	oral solution	oral use
Slovak Republic	Zentiva a.s. Nitrianska 100 Hlohovec 920 27 Slovak Republic	bromhexine hydrochloride, mentholum, oleum foeniculi, oleum anisi, oleum origani, oleum menthae piperitae, oleum eucalypti	BRONCHOSAN	8 mg/ml 1,5 mg/ml 0,75 mg/ml 0,250 mg/ml 0,250 mg/ml 0,250 mg/ml 0,250 mg/ml	oral drops	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovenia	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein Germany	bromhexine hydrochloride	BISOLVON 4 mg/5 ml sirup	4 mg/5 ml	syrup	oral use
Slovenia	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein Germany	bromhexine hydrochloride	Bisolvon 8 mg tablete	8 mg	tablet	oral use
Slovenia	Boehringer Ingelheim International GmbH Binger Strasse 173 D-55216 Ingelheim am Rhein Germany	bromhexine hydrochloride	Bisolvon 2 mg/ml peroralna raztopina/ inhalacijska raztopina za nebulator	2 mg/ml	oral solution/ nebuliser solution	oral use, inhalation use
Slovenia	KRKA, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	ambroxol hydrochloride	Solvolan 3 mg/ml sirup	3 mg/ml	syrup	oral use
Slovenia	KRKA, d.d., Novo mesto Šmarješka cesta 6 8000 Novo mesto Slovenia	ambroxol hydrochloride	Solvolan 30 mg tablete	30 mg	tablet	oral use
Slovenia	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed 3 mg/ml peroralna raztopina	3 mg/ml	oral solution	oral use
Slovenia	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed 30 mg tablete	30 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Slovenia	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed 6 mg/ml peroralna raztopina	6 mg/ml	oral solution	oral use
Slovenia	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Flavamed 60 mg šumeče tablete	60 mg	effervescent tablet	oral use
Slovenia	Medis, d.o.o. Brnčičeva 1 1000 Ljubljana Slovenia	ambroxol hydrochloride	Ambrospray 10 mg/vpih peroralna raztopina	10 mg/spray puff	oral solution	oral use
Slovenia	BERLIN-CHEMIE AG Glienicker Weg 125 12489 Berlin Germany	ambroxol hydrochloride	Ambroksolijev klorid Berlin-Chemie 6 mg/ml peroralna raztopina	6 mg/ml	oral solution	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Motosol 3 mg/ml jarabe	3 mg/ml	syrup	oral use
Spain	ARISTO PHARMA IBERICA, S.L. Solana, 26 28850 Torrejón de Ardoz Madrid Spain	Ambroxol hydrochloride	Ambroxol Edigen jarabe EFG	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	LABORATORIOS CINFA S.A. Olaz-Chipi, 10 Poligono Indistrial Areta 31620 Huarte-Pamplona Navarra Spain	Ambroxol hydrochloride	Ambroxol cinfa 15 mg/5 ml jarabe EFG	15 mg/5 ml	syrup	oral use
Spain	LABORATORIOS NORMON S.A. Ronda de Valdecarrizo, 6 28760 Tres Cantos Madrid Spain	Ambroxol hydrochloride	Ambroxol Normon 3 mg/ml solucion EFG	3 mg/ml	oral solution	oral use
Spain	APOTEX EUROPE B.V: Darwinweg, 20 2333 CR Leiden The Netherlands	Ambroxol hydrochloride	Ambroxol Apotex 15 ml/5 ml jarabe EFG	15 mg/5 ml	syrup	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan 30 mg comprimidos	30 mg	tablet	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Motosol 7,5 mg/ml solucion inyectable	7,5 mg/ml	solution for injection	intravenous use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan Pediátrico 3 mg/ml jarabe	3 mg/ml	syrup	oral use
Spain	FERRER INTERNACIONAL S.A. Gran Via Carlos III, 94 08028 Barcelona Spain	Ambroxol hydrochloride	Naxpa jarabe	15 mg/5 ml	syrup	oral use
Spain	LABORATORIOS NORMON S.A. Ronda de Valdecarrizo, 6 28760 Tres cantos Madrid Spain	Ambroxol hydrochloride	Mucibron 3 mg/ml solucion oral	3 mg/ml	oral solution	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan Retard 75 mg cápsulas de liberación prolongada	75 mg	prolonged-release capsule, hard	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Motosol Retard 75 mg cápsulas de liberación prolongada	75 mg	prolonged-release capsule, hard	oral use
Spain	WAAS_ANITA S.A. General Prim 13 28035 Madrid Spain	Ambroxol hydrochloride	Dinobroxol jarabe	15 mg/5 ml	syrup	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan 60 mg polvo para solución oral	15 mg/5 ml	powder for oral suspension	oral use
Spain	RATIOPHARM ESPAÑA S.A. Avda Burgos, 16 D 5ª Planta 28036 Madrid Spain	ambroxol hydrochloride	Ambroxol ratiopharm 3 mg/ml jarabe EFG	3 mg/ml	syrup	oral use
Spain	SANDOZ FARMACEUTICA S.A. Avda Osa Mayor, 4 28023 Aravaca Madrid Spain	Ambroxol hydrochloride	Ambroxol Sandoz 3 mg/ml jarabe EFG	3 mg/ml	syrup	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan 6 mg/ml jarabe	6 mg/ml	syrup	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan 15 mg pastillas de goma	15 mg	oral gum	oral use
Spain	CYATHUS EXQUIRERE PHARMA-FORSCHUNGS GMBH Rudolfsplatz 2/1/8 1010 Viena Austria	Ambroxol hydrochloride	Ambroxol Exquirere 10 mg pulsación solucion oral	10 mg/pulsation	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	LABORATORIOS VICKS S.L. Avda Bruselas, 24 28108 Alcobendas Madrid Spain	Ambroxol hydrochloride	Formulamucol 6 mg/ml solución oral EFG	6 mg/ml	oral solution	oral use
Spain	LABORATORIOS VICKS S.L. Avda Bruselas, 24 28108 Alcobendas Madrid Spain	Ambroxol hydrochloride	Formulamucol 3 mg/ml solución oral EFG	3 mg/ml	oral solution	oral use
Spain	TEVA PHARMA S.L.U. C/Anabel Segura 11 Edificio Albatros B 1ª Planta 28108 Alcobendas Madrid Spain	Ambroxol hydrochloride	Ambroxol Tevapharma 3 mg/ml solución	3 mg/ml	oral solution	oral use
Spain	TEVA PHARMA S.L.U. C/Anabel Segura 11 Edificio Albatros B 1ª Planta 28108 Alcobendas Madrid Spain	Ambroxol hydrochloride	Ambroxol Tevapharma 6 mg/ml solución	6 mg/ml	oral solution	oral use
Spain	RATIOPHARM ESPAÑA S.A. C/Anabel Segura 11 Edificio Albatros B 1ª Planta 28108 Alcobendas Madrid Spain	Ambroxol hydrochloride	Ambroxol ratio 6 mg/ml solucion oral EFG	6 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	RATIOPHARM ESPAÑA S.A. C/Anabel Segura 11 Edificio Albatros B 1ª Planta 28108 Alcobendas Madrid Spain	Ambroxol hydrochloride	Ambroxol ratio 3 mg/ml solución oral EFG	3 mg/ml	oral solution	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Lizipadol 20 mg pastillas para chupar	20 mg	lozenge	oromucosal use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Ambroxol hydrochloride	Mucosan 30 mg jarabe en sobres	30 mg	syrup	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Bromhexine hydrochloride	Bisolmed 2 mg/ml solución inyectable y para perfusión	2 mg/ml	solution for injection/infusion	intravenous use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Bromhexine hydrochloride	Bisolmed 2 mg/ml solución oral/concentrado para solución para inhalación por nebulizador	2 mg/ml	oral solution/ concentrate for nebuliser solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	LABORATORIOS CINFA S.A. Olaz-Chipi, 10 Poligono Indistrial Areta 31620 Huarte Pamplona Navarrra Spain	Bromhexine hydrochloride + Sulfamethoxazole hydrochloride + Trimethoprim + balsam tolu aqueous extract	Bactopumon	2 mg + 400 mg + 80 mg + 75 mg/5 ml	oral suspension	oral use
Spain	DESMA LABORATORIO FARMACEUTICO, S.L. Cuatro amigos 7, escalera 2, 1°D 28029 Madrid Spain	bromhexine hydrochloride + Sulfamethoxazole hydrochloride + Trimethoprim	Balsoprim suspensión	50 mg + 2 660 mg + 540 mg/100 ml	oral suspension	oral use
Spain	FAES FARMA, S.A. Maximo Aguirre, 14 48940 Lamiaco-Lejona Vizcaya Spain	Bromhexine hydrochloride + benzoate sodium + Sulfamethoxazole + Trimethoprim + Balsam Tolú syrup	Bronquidiazina CR suspensión	4 mg + 250 mg + 400 mg + 80 mg + 325 mg/7,5 ml	oral suspension	oral use
Spain	GLAXOSMITHKLINE, S.A. Severo Ochoa, 2 28760 Tres Cantos Madrid Spain	Bromhexine hydrochloride + Amoxicilin trihydrate	Clamoxyl mucolítico 500 mg cápsulas	8 mg + 500 mg	capsule, hard	oral use
Spain	GLAXOSMITHKLINE, S.A. Severo Ochoa, 2 28760 Tres Cantos Madrid Spain	Bromhexine hydrochloride + Amoxicilin trihydrate	Clamoxyl mucolítico 250 mg suspensión extemporánea	4 mg + 250 mg/5 ml	powder for oral suspension	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Bromhexine hydrochloride	Bisolvon mucolítico 1,6 mg/ml jarabe	8 mg/5 ml	syrup	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Bromhexine hydrochloride	Bisolvon mucolítico 8 mg comprimidos solubles	8 mg	soluble tablet	oral use
Spain	BOEHRINGER INGELHEIM ESPAÑA, S.A. Prat de la Riba, 50 08174 Sant Cugat del Vallés Barcelona Spain	Bromhexine hydrochloride	Bisolvon mucolítico infantil 0,8 mg/ml jarabe	0,8 mg/ml	syrup	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Ambroxolol hydrochloride	Mucoangin Svartvinbär	20 mg	lozenge	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Ambroxolol hydrochloride	Mucoangin	20 mg	lozenge	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Ambroxolol hydrochloride	Mucoangin Citron	20 mg	lozenge	oral use
Sweden	BioPhausia AB, Blasieholmsgatan 2, 111 48 Stockholm, Sweden	Bromhexine hydrochloride + ephedrine hydrochloride	Mollipect	0,5 mg/ml + 1 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Sweden	Apofri AB, Box 120, 182 12 Danderyd, Sweden	Bromhexine hydrochloride	Bromhexin Apofri	0,8 mg/ml	oral solution	oral use
Sweden	Apofri AB, Box 120, 182 12 Danderyd, Sweden	Bromhexine hydrochloride	Bromhexin Apofri	1,6 mg/ml	oral solution	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	8 mg	tablet	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	0,8 mg/ml	oral solution	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	1,6 mg/ml	oral solution	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon	8 mg	soluble tablet	oral use
Sweden	Boehringer Ingelheim International GmbH, Binger Strasse 173, DE-55216 Ingelheim am Rhein, Germany	Bromhexine hydrochloride	Bisolvon Jordgubb	0,8 mg/ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
Sweden	McNeil Sweden AB, 169 90 Solna, Sweden	Bromhexine hydrochloride	Bromhex	0,8 mg/ml	oral solution	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	ambroxol hydrochloride	Mucoangin, zuigtabletten 20 mg	20 mg	lozenge	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	ambroxol hydrochloride	Mucoangin Citroen 20 mg, zuigtabletten	20 mg	lozenge	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	ambroxol hydrochloride	Rexambro 20 mg, zuigtabletten	20 mg	lozenge	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	bromhexine hydrochloride	Bisolvon drank in sachet, 8 mg	8 mg	oral solution in sachet	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	bromhexine hydrochloride	Bisolvon drank voor kinderen met aardbeiensmaak, 4 mg/5 ml	4 mg/5 ml	oral solution	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	bromhexine hydrochloride	Bisolvon drank voor kinderen, 4 mg/5 ml	4 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	bromhexine hydrochloride	Bisolvon drank, 8 mg/5 ml	8 mg/5 ml	oral solution	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	bromhexine hydrochloride	Bisolvon druppels voor kinderen, oplossing 2 mg/ml	2 mg/ml	oral solution	oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	bromhexine hydrochloride	Bisolvon tabletten, 8 mg	8 mg	tablet	oral use
The Netherlands	Sameko BV Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Broomhexine HCI 8 mg Sameko, tabletten	8 mg	tablet	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC ETTEN LEUR The Netherlands	bromhexine hydrochloride	Broomhexine HCl CF 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC ETTEN LEUR The Netherlands	bromhexine hydrochloride	Broomhexine HCl CF 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC ETTEN LEUR The Netherlands	bromhexine hydrochloride	Broomhexine HCl CF 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Basic Pharma Manufacturing bv Burgemeester Lemmensstraat 352 6163 JT GELEEN The Netherlands	bromhexine hydrochloride	Broomhexine HCl drank 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Basic Pharma Manufacturing bv Burgemeester Lemmensstraat 352 6163 JT GELEEN The Netherlands	bromhexine hydrochloride	Broomhexine HCl drank 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Apotex Europe B.V. Darwinweg 20 2333 CR LEIDEN The Netherlands	bromhexine hydrochloride	Broomhexine HCl hoestdrank extra sterk suikervrij Apotex 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Apotex Europe B.V. Darwinweg 20 2333 CR LEIDEN The Netherlands	bromhexine hydrochloride	Broomhexine HCl hoestdrank suikervrij Apotex 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Apotex Europe B.V. Darwinweg 20 The Netherlands	bromhexine hydrochloride	Broomhexine HCl Apotex 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Mediq Farma B.V. Hertogswetering 159 3543 AS UTRECHT The Netherlands	bromhexine hydrochloride	Broomhexine HCl Mdq 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Mediq Farma B.V. Hertogswetering 159 3543 AS UTRECHT The Netherlands	bromhexine hydrochloride	Broomhexine HCl Mdq 8 mg, tabletten	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Mediq Farma B.V. Hertogswetering 159 3543 AS UTRECHT The Netherlands	bromhexine hydrochloride	Broomhexine HCl Mdq 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	RXT Amsterdamsestraatweg 22 1391 AB ABCOUDE The Netherlands	bromhexine hydrochloride	Broomhexine HCl RXT 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Nederlandse Service Apotheek Beheer B. V. Vonderweg 39a 7468 DC ENTER The Netherlands	bromhexine hydrochloride	Broomhexine HCI SAM 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH ALMERE The Netherlands	bromhexine hydrochloride	Broomhexine HCl Sandoz 0,8 mg/ml, drank	0,8 mg/ml	oral solution	oral use
The Netherlands	MAE Holding BV Amsterdamsestraatweg 22 1391 AB ABCOUDE The Netherlands	bromhexine hydrochloride	Broomhexine HCl Triangle Pharma 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	MAE Holding BV Amsterdamsestraatweg 22 1391 AB ABCOUDE The Netherlands	bromhexine hydrochloride	Broomhexine HCl Triangle Pharma 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	bromhexine hydrochloride	Broomhexine HCl 4=5 PCH, drank 4 mg/5 ml	4 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Basic Pharma Manufacturing bv Burgemeester Lemmensstraat 352 6163 JT GELEEN The Netherlands	bromhexine hydrochloride	Broomhexine HCl 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	bromhexine hydrochloride	Broomhexine HCl 8 PCH, tabletten 8 mg	8 mg	tablet	oral use
The Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	bromhexine hydrochloride	Broomhexine HCl 8=5 PCH, drank 8 mg/5 ml	8 mg/5 ml	oral solution	oral use
The Netherlands	Samenwerkende Apothekers Nederland B.V. Kralingseweg 201 3062 CE ROTTERDAM The Netherlands	bromhexine hydrochloride	Broomhexinehydrochloride 8 mg tabletten Samenwerkende Apothekers	8 mg	tablet	oral use
The Netherlands	Sameko BV Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	C1000 Hoestdrank Broomhexine HCl 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Sameko BV Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	C1000 Hoestdrank Extra Sterk Broomhexine HCI 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Sameko BV Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	C1000 Hoesttabletten Broomhexine HCl 8 mg, tabletten	8 mg	tablet	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	HEMA B.V. NDSM-straat 10 1033 SB AMSTERDAM The Netherlands	bromhexine hydrochloride	HEMA Hoestdrank Broomhexine HCl 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	HEMA B.V. NDSM-straat 10 1033 SB AMSTERDAM The Netherlands	bromhexine hydrochloride	HEMA Hoestdrank Broomhexine HCl 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	HEMA B.V. NDSM-straat 10 1033 SB AMSTERDAM The Netherlands	bromhexine hydrochloride	HEMA Hoesttabletten Broomhexine HCl 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	HTP Huisapotheek B.V. Nieuwe Donk 3 4879 AC ETTEN-LEUR The Netherlands	bromhexine hydrochloride	Hoestdrank Broomhexine HCl 4 mg/5 ml HTP Huisapotheek, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	HTP Huisapotheek B.V. Nieuwe Donk 3 4879 AC ETTEN-LEUR The Netherlands	bromhexine hydrochloride	Hoestdrank Broomhexine HCl 8 mg/5 ml HTP Huisapotheek, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	HTP Huisapotheek B.V. Nieuwe Donk 3 4879 AC ETTEN-LEUR The Netherlands	bromhexine hydrochloride	Hoesttabletten Broomhexine HCl 8 mg HTP Huisapotheek, tabletten	8 mg	tablet	oral use
The Netherlands	SDG Farma B.V. Treubweg 11 1112 BA DIEMEN The Netherlands	bromhexine hydrochloride	IDYL Hoestdrank Broomhexine HCl 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	SDG Farma B.V. Treubweg 11 1112 BA DIEMEN The Netherlands	bromhexine hydrochloride	IDYL Hoesttabletten Broomhexine HCl 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Jumbo Supermarkten B.V. Rijksweg 15 5462 CE VEGHEL The Netherlands	bromhexine hydrochloride	JUMBO Hoestdrank Broomhexine HCl 4 mg/5 ml suikervrij, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Jumbo Supermarkten B.V. Rijksweg 15 5462 CE VEGHEL The Netherlands	bromhexine hydrochloride	JUMBO hoestdrank extra sterk broomhexine HCl 8 mg/5 ml suikervrij, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Jumbo Supermarkten B.V. Rijksweg 15 5462 CE VEGHEL The Netherlands	bromhexine hydrochloride	JUMBO hoesttabletten broomhexine HCl 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Kruidvat HOESTDRANK Broomhexine HCl 4 mg/5 ml suikervrij, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Kruidvat HOESTDRANK Extra sterk Boomhexine HCl 8 mg/5 ml suikervrij, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Leidapharm B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Leidapharm Hoestdrank Broomhexine HCl 4 mg/5 ml suikervrij, drank	4 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Leidapharm B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Leidapharm Hoestdrank Extra sterk Broomhexine HCl 8 mg/5 ml suikervrij, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Nedac Sorbo B.V. Innovatie 1 6921 RN DUIVEN The Netherlands	bromhexine hydrochloride	NEDAC SORBO Hoestdrank Broomhexine HCl 4 mg/5 ml suikervrij, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Nedac Sorbo B.V. Innovatie 1 6921 RN DUIVEN The Netherlands	bromhexine hydrochloride	NEDAC SORBO Hoestdrank Extra Sterk Broomhexine HCl 8 mg/5 ml suikervrij, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Nedac Sorbo B.V. Innovatie 1 6921 RN DUIVEN The Netherlands	bromhexine hydrochloride	NEDAC SORBO Hoesttabletten Broomhexine HCl 8 mg, tabletten	8 mg	tablet	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten-Leur The Netherlands	bromhexine hydrochloride	Otrivin Broomhexine HCI 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten-Leur The Netherlands	bromhexine hydrochloride	Otrivin Broomhexine HCl 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Trekpleister HOESTDRANK Broomhexine HCl 4 mg/5 ml suikervrij, drank	4 mg/5 ml	oral solution	oral use

Member State in EEA	Marketing authorisation holder	INN	Invented name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Trekpleister HOESTDRANK Broomhexine HCl 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Trekpleister HOESTDRANK Extra sterk Broomhexine HCl 8 mg/5 ml suikervrij, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Trekpleister HOESTDRANK EXTRA STERK Broomhexine HCl 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Marel B.V. Archimedesweg 2 2333 CN LEIDEN The Netherlands	bromhexine hydrochloride	Trekpleister hoesttabletten bij vastzittende hoest 8, tabletten 8 mg	8 mg	tablet	oral use
The Netherlands	Procter & Gamble Nederland B.V. Watermanweg 100 3067 GG ROTTERDAM The Netherlands	bromhexine hydrochloride	Vicks Hoestdrank broomhexinehydrochloride 8 mg/5 ml, drank	8 mg/5 ml	oral solution	oral use
The Netherlands	Procter & Gamble Nederland B.V. Watermanweg 100 3067 GG ROTTERDAM The Netherlands	bromhexine hydrochloride	Vicks Hoestdrank voor Kinderen broomhexinehydrochloride 4 mg/5 ml, drank	4 mg/5 ml	oral solution	oral use