Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 June 2016 to 30 June 2016

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

(2016/C 277/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
29.6.2016	Inhaled corticosteroids	beclomethasone, budesonide, flunisolide, fluticasone propionate, fluticasone furoate	See Annex I	See Annex I	30.6.2016
10.6.2016	CattleMarker IBR Inactivated emulsion for injec	Inactivated gE Bovine Herpes Virus type 1 (BoHv-1), strain Difivac	See Annex II	See Annex II	13.6.2016
24.6.2016	Novantrone and associated names	mitoxantrone	See Annex III	See Annex III	27.6.2016
24.6.2016	Irbesartan	Irbesartan	Not applicable	Not applicable	27.6.2016
29.6.2016	Zoledronic acid	Zoledronic acid	Not applicable	Not applicable	30.6.2016

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

ANNEX I

List of nationally authorised medicinal products

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	3m Health Care Ltd	Aerocortin	Beclometasone Dipropionate 50 µg/50 µl	Pressurised Inhalation, Solution
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonpropionat	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation, Suspension
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonpropionat Diskus Forte Allen	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonpropionat Diskus Junior Allen	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonpropionat 'allen'	Fluticasone Propionate 125 µg Dose	Pressurised Inhalation, Suspension
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonpropionat 'allen'	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonpropionat 'allen'	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Samtoral Diskus Standard	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Astrazeneca österreich Gmbh	Pulmicort	Budesonide 400 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Pulmicort Turbohaler	Budesonide 100 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Astrazeneca österreich Gmbh	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Symbicort Forte Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Austria	Chiesi Pharmaceuticals Gmbh	Budiair	Budesonide 0,2 mg/0,05ml	Pressurised Inhalation, Solution
Austria	Chiesi Pharmaceuticals Gmbh	Budiair Jet	Budesonide 0,2 mg/0,05 ml	Pressurised Inhalation, Solution
Austria	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Austria	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide Diskus Forte	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide Diskus Junior	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide Junior	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension
Austria	Glaxosmithkline Pharma Gmbh.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Pari Pharma Gmbh	Buparid	Budesonide 0,25 mg Ampoule	Nebuliser Suspension
Austria	Pari Pharma Gmbh	Buparid	Budesonide 0,5 mg Ampoule	Nebuliser Suspension
Austria	Pari Pharma Gmbh	Buparid	Budesonide 1 mg Ampoule	Nebuliser Suspension
Austria	Sandoz Gmbh	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Sandoz Gmbh	Airflusal Forspiro	Fluticasone Propionate 465 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder
Belgium	Chiesi Sa-Nv	Inuvair	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Belgium	Cipla Europe Nv	Salmeterol/Fluticasone Cipla	Salmeterol 25 µg/Dose; Fluticasone Propionate 125 µg/Dose	Pressurised Inhalation, Suspension
Belgium	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Belgium	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 0,05 mg/2ml	Nebuliser Solution
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 2 mg/2ml	Nebuliser Solution
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Belgium	Nv Astrazeneca Sa	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Belgium	Nv Astrazeneca Sa	Symbicort Forte Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Belgium	Nv Astrazeneca Sa	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Belgium	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Belgium	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Belgium	Pari Pharma Gmbh	Buparid	Budesonide 0,25 mg Ampoule	Nebuliser Suspension
Belgium	Pari Pharma Gmbh	Buparid	Budesonide 0,5 mg Ampoule	Nebuliser Suspension

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Belgium	Pari Pharma Gmbh	Buparid	Budesonide 1 mg Ampoule	Nebuliser Suspension
Belgium	Sandoz N.V.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Bulgaria	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Bulgaria	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Bulgaria	Chiesi Pharmaceuticals Gmbh	Foster	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Bulgaria	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Bulgaria	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Bulgaria	Glaxosmithkline Eood	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Bulgaria	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Bulgaria	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Bulgaria	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Bulgaria	Sopharma Ad	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Croatia	Astrazeneca D.O.O	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Croatia	Astrazeneca D.O.O	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Croatia	Clinres Farmacija D.O.O.	Dimenium	Fluticasone Propionate 100 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Clinres Farmacija D.O.O.	Dimenium	Fluticasone Propionate 250 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Croatia	Clinres Farmacija D.O.O.	Dimenium	Fluticasone Propionate 500 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Glaxosmithkline D.O.O.	Salmeterol/Flutikazon-propionat Diskus Glax-osmithkline	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Glaxosmithkline D.O.O.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Providens D.O.O.	Foster	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Ac-tuation	Pressurised Inhalation, Solution
Croatia	Salvus D.O.O.	Saldisk	Fluticasone Propionate 100 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Salvus D.O.O.	Saldisk	Fluticasone Propionate 250 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Salvus D.O.O.	Saldisk	Fluticasone Propionate 500 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Sandoz D.O.O.	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Croatia	Sandoz D.O.O.	Airflusal Forspiro	Fluticasone Propionate 465 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Cyprus	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Cyprus	Costakis Tsisios & Co. Ltd	Fluticapen	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Fluticapen	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Pulmoton	Budesonide 100 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Pulmoton	Budesonide 200 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Pulmoton	Budesonide 400 µg Dose, Formoterol Fumarate Dihydrate 12 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Rolenium	Fluticasone Propionate 100 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Cyprus	Costakis Tsisios & Co. Ltd	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Cyprus	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Cyprus	Glaxo Group Limited	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Cyprus	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Cyprus	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Cyprus	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Czech Republic	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Czech Republic	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Czech Republic	Chiesi Pharmaceuticals Gmbh	Combair	Formoterol Fumarate Dihydrate 1,08 Mg, Beclometasone Dipropionate 18 Mg	Pressurised Inhalation, Solution
Czech Republic	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Czech Republic	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Czech Republic	Glaxo Group Limited	Flixotide	Fluticasone Propionate 125 µg	Pressurised Inhalation, Suspension
Czech Republic	Glaxo Group Limited	Flixotide	Fluticasone Propionate 250 µg	Pressurised Inhalation, Suspension
Czech Republic	Glaxo Group Limited	Flixotide	Fluticasone Propionate 50 µg	Pressurised Inhalation, Suspension
Czech Republic	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 100 µg	Inhalation Powder
Czech Republic	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 250 µg	Inhalation Powder
Czech Republic	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 500 µg	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Czech Republic	Glaxo Group Limited	Seretide Diskus	Fluticasone Propionate 500 µg, Salmeterol Xinafoate 72,5 µg	Inhalation Powder
Czech Republic	Sandoz S.R.O.	Airflusan Forspiro	Fluticasone Propionate 0,25 Mg, Salmeterol Xinafoate 0,073 Mg	Inhalation Powder, Pre-Dispensed
Czech Republic	Sandoz S.R.O.	Airflusan Forspiro	Fluticasone Propionate 0,5 Mg, Salmeterol Xinafoate 0,073 Mg	Inhalation Powder, Pre-Dispensed
Denmark	Astrazeneca A-S	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Denmark	Astrazeneca A-S	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Denmark	Chiesi Farmaceutici S.P.A.	Innovair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Denmark	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Denmark	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose, Lactose Monohydrate 24,677 mg Dose	Inhalation Powder, Pre-Dispensed
Denmark	Glaxosmithkline Pharma A-S	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Denmark	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Denmark	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Denmark	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Denmark	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 465 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Estonia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Estonia	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Estonia	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Estonia	Glaxo Wellcome Ltd	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Estonia	Glaxo Wellcome Ltd	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Finland	Astrazeneca Oy	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Finland	Astrazeneca Oy	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Finland	Chiesi Farmaceutici S.P.A.	Innovair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Finland	Chiesi Farmaceutici S.P.A.	Innovair Nexthaler	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Inhalation Powder
Finland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Finland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Finland	Glaxosmithkline Oy	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Finland	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Finland	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
France	Astrazeneca France	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
France	Astrazeneca France	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
France	Chiesi S.A.	Formodual	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Pressurised Inhalation, Solution
France	Chiesi S.A.	Innovair	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Pressurised Inhalation, Solution
France	Laboratoire Glaxosmithkline S.A.S.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	3m Health Care Ltd	Bronchocort Novo	Beclometasone Dipropionate 100 µg/50 µl	Pressurised Inhalation, Solution
Germany	3m Health Care Ltd	Junik	Beclometasone Dipropionate 100 µg Actuation	Pressurised Inhalation, Solution
Germany	Abz-Pharma Gmbh	Beclomethasone Dipropionate Ct	Beclometasone Dipropionate 0,05 mg/18,7 G	Pressurised Inhalation, Solution
Germany	Meda Pharma Gmbh & Co. Kg	Budecort Novolizer	Budesonide, Micronised 0,2 mg Actuation	Inhalation Powder
Germany	Meda Pharma Gmbh & Co. Kg	Budecort Novolizer	Budesonide, Micronised 0,4 mg Actuation	Inhalation Powder
Germany	Astrazeneca Gmbh	Pulmicort Budesonide	Budesonide 0,5 Mg	Nebuliser Suspension
Germany	Astrazeneca Gmbh	Pulmicort Budesonide	Budesonide 1,0 Mg	Nebuliser Suspension
Germany	Astrazeneca Gmbh	Pulmicort	Budesonide 400 µg Dose	Inhalation Powder
Germany	Astrazeneca Gmbh	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Germany	Astrazeneca Gmbh	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Germany	Astrazeneca Gmbh	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Chiesi Farmaceutici S.P.A.	Kantos	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Germany	Chiesi Farmaceutici S.P.A.	Kantos Master	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Budiair	Budesonide 200 µg Spray	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Ribuvent	Budesonide 200 µg Puff	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Sanasthmax	Beclometasone Dipropionate 250 µg/59,2 Mg	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Sanasthmax Junior	Beclometasone Dipropionate 50 µg/59 Mg	Pressurised Inhalation, Solution
Germany	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Glaxosmithkline Gmbh & Co. Kg	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Germany	Glaxosmithkline Gmbh & Co. Kg	Flixotide Forte	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Germany	Glaxosmithkline Gmbh & Co. Kg	Flixotide Forte Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Germany	Glaxosmithkline Gmbh & Co. Kg	Flutide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Glaxosmithkline Gmbh & Co. Kg	Flutide Forte	Fluticasone Propionate 220 µg Puff	Pressurised Inhalation, Suspension
Germany	Glaxosmithkline Gmbh & Co. Kg	Flutide Forte Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Glaxosmithkline Gmbh & Co. Kg	Viani Forte	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Budesonid	Budesonide 0,2 Mg	Inhalation Powder
Germany	Hexal Ag	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Hexal Ag	Budes N	Budesonide 0,2 mg Dose	Pressurised Inhalation, Solution
Germany	Janssen-Cilag Gmbh	Inuvair	Beclometasone Dipropionate 100 µg Inhalation, Formoterol Fumarate 6 µg Inhalation	Pressurised Inhalation, Solution
Germany	Meda Pharma Gmbh & Co. Kg	Budesonid Novolizer Meda Pharma Gmbh & Co. Kg	Budesonide 400 µg Inhalation	Inhalation Powder
Germany	Meda Pharma Gmbh & Co. Kg	Novopulmon Novolizer	Budesonide 200 µg Dose	Inhalation Powder
Germany	Meda Pharma Gmbh & Co. Kg	Novopulmon Novolizer	Budesonide 400 µg Dose	Inhalation Powder
Germany	Mylan Dura Gmbh	Budesonid Mylan	Budesonide 0,2 Mg	Inhalation Powder
Germany	Orion Corporation	Beclomet Easyhaler	Beclometasone Dipropionate 0,2 mg Dose	Inhalation Powder
Germany	Pari Pharma Gmbh	Buparid	Budesonide 0,25 mg Ampoule	Nebuliser Suspension
Germany	Pari Pharma Gmbh	Buparid	Budesonide 0,5 mg Ampoule	Nebuliser Suspension
Germany	Pari Pharma Gmbh	Buparid	Budesonide 1 mg Ampoule	Nebuliser Suspension
Germany	Pb Pharma Gmbh	Budesonid	Budesonide 0,92 Mg	Inhalation Powder, Hard Capsule

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Pb Pharma Gmbh	Cyclocaps Beclometason	Beclometasone Dipropionate 100 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Beclometason	Beclometasone Dipropionate 200 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Beclometason	Beclometasone Dipropionate 400 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Budesonid	Budesonide 0,8 mg Capsule	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Budesonid	Budesonide 100 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Budesonid	Budesonide 800 µg Units	Inhalation Powder, Hard Capsule
Germany	Ratiopharm Gmbh	Beclometason Ratio-pharm	Beclometasone Dipropionate 0,25 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Ratiopharm Gmbh	Beclomethasone Dipro-pionate Ratiopharm	Beclometasone Dipropionate 0,05 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Ratiopharm Gmbh	Beclomethasone Dipro-pionate Ratiopharm	Beclometasone Dipropionate 0,1 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Ratiopharm Gmbh	Beclomethasone Dipro-pionate Ratiopharm	Beclometasone Dipropionate 0,2 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Aerobec N	Beclometasone Dipropionate 100 g/5ml	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Teva Gmbh	Beclometason-Ct	Beclometasone Dipropionate 0,1 Mg	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Beclometason-Ct	Beclometasone Dipropionate 0,2 Mg	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 100 g/10ml	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 100 g/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 100 g/5ml	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 250 g/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 250 g/78 mg	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair Mite	Beclometasone Dipropionate 50 g/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair Mite	Beclometasone Dipropionate 50 g/78 mg	Pressurised Inhalation, Solution
Germany	Ucb Pharma Gmbh (Monheim De)	Atmadisc Forte Diskus	Fluticasone Propionate 500 µg Inhalation, Salmeterol 50 µg Inhalation	Inhalation Powder
Greece	Anfarm Hellas Sa	Talgan	Budesonide 100 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Pulmicort Turbuhaler	Budesonide 400 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Astrazeneca S.A.	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Greece	Chiesi Hellas A.E.B.E.	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Greece	Chiesi Hellas A.E.B.E.	Foster Nexthaler	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Inhalation Powder
Greece	Chiesi Hellas A.E.B.E.	Inuvair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Greece	Chiesi Hellas A.E.B.E.	Inuvair Nexthaler	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Inhalation Powder
Greece	D.A.S.T. Biotech Pharm επε	Flihaler	Fluticasone Propionate 250mcg/Dose	Pressurised Inhalation, Suspension
Greece	Elpen Pharmaceutical Co. Inc.	Fluticapen	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Fluticapen	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Pulmoton	Budesonide 100 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Pulmoton	Budesonide 200 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Elpen Pharmaceutical Co. Inc.	Pulmoton	Budesonide 400 µg Dose, Formoterol Fumarate Dihydrate 12 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 125 µg Dose	Pressurised Inhalation
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation
Greece	Glaxosmithkline Aebe	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Iasis Pharma	Olfo Haler	Budesonide 200 µg Dose	Inhalation Powder
Greece	Iasis Pharma	Olfo Haler	Budesonide 400 µg Dose	Inhalation Powder
Greece	Medicair Bioscience Laboratories S.A	Bocacort-S	Fluticasone Propionate 250mcg/Dose	Pressurised Inhalation, Suspension
Greece	Orion Corporation	Bufomix	Budosenide 160mcg, Formoterol Fumarate Dihydrate 4,5mcg	Inhalation Powder
Greece	Orion Corporation	Bufomix	Budosenide 320mcg, Formoterol Fumarate Dihydrate 9mcg	Inhalation Powder
Greece	Orion Corporation	Orest	Budosenide 160mcg, Formoterol Fumarate Dihydrate 4,5mcg	Inhalation Powder
Greece	Orion Corporation	Orest	Budosenide 320mcg, Formoterol Fumarate Dihydrate 9mcg	Inhalation Powder
Greece	Png Gerolymatos Medical A.E.	Asmaflex	Fluticasone Propionate 250mgg	Pressurised Inhalation, Suspension
Greece	Rafarm Sa.	Resata	Budesonide 200 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Rafarm Sa.	Resata	Budesonide 400 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Verisfield (Uk) Ltd	Flixocort	Fluticasone Propionate 50 µg Dose	Nasal Spray, Suspension
Greece	Verisfield (Uk) Ltd	Flixocort	Fluticasone Propionate 125 µg Dose	Pressurised Inhalation, Suspension
Greece	Verisfield (Uk) Ltd	Flixocort	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Greece	Verisfield (Uk) Ltd	Pulmihal	Budesonide 200 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Win Medica Ltd	Flusalair	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Greece	Win Medica Ltd	Flusalair	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Win Medica Ltd	Flutiresp	Fluticasone Propionate 250mcg/Dose	Inhalation Powder
Greece	Win Medica Ltd	Flutiresp	Fluticasone Propionate 500 µg Inhalation	Inhalation Powder
Greece	Zwitter Pharmaceuticals επε	Salenga	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Greece	Pharmanel Commercial Pharmaceutical S.A.	Vernoral	Budesonide 200 µg Dose	Inhalation Powder
Greece	Pharmanel Commercial Pharmaceutical S.A.	Vernoral	Budesonide 400 µg Dose	Inhalation Powder
Hungary	Astrazeneca Kft.	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Hungary	Astrazeneca Kft.	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Hungary	Chiesi Pharmaceuticals Gmbh	Formodual	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Hungary	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Hungary	Elpen Pharmaceutical Co. Inc.	Dimenio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Hungary	Elpen Pharmaceutical Co. Inc.	Dimenio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Hungary	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Glaxosmithkline Kft.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Montrose Kft	Thoreus Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Hungary	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Hungary	Sandoz Hungária Kft	Airflusol Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Iceland	Astrazeneca A-S	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Iceland	Astrazeneca A-S	Symbicort Mite Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Iceland	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Iceland	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Iceland	Glaxosmithkline Ehf.	Flixotide	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Iceland	Glaxosmithkline Ehf.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Iceland	Glaxosmithkline Ehf.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Iceland	Glaxosmithkline Ehf.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Iceland	Glaxosmithkline Ehf.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Astrazeneca Uk Limited	Pulmicort Turbohaler	Budesonide 100 µg Dose	Inhalation Powder
Ireland	Astrazeneca Uk Limited	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Ireland	Astrazeneca Uk Limited	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Ireland	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Ireland	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Ireland	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose, Lactose Monohydrate 24,677 mg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Flixotide Diskus	Fluticasone Propionate 250 µg Blister	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Flixotide Diskus	Fluticasone Propionate 500 µg Blister	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Flixotide Evohaler	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Ireland	Glaxosmithkline (Ireland) Limited	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Viani Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Ireland	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Ireland	Rowex Ltd	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Ireland	Rowex Ltd	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Sinestic	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Sinestic	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Symbicort	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Symbicort	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Italy	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Italy	Glaxosmithkline S.P.A.	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Menarini International Operations Luxembourg S.A.	Aliflus Diskus	Fluticasone Propionate 100 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Menarini International Operations Luxembourg S.A.	Aliflus Diskus	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Menarini International Operations Luxembourg S.A.	Aliflus Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Promedica S.R.L.	Clenil Compositum	Beclometasone Dipropionate 0,8 mg/2 Ml, Salbutamol Sulfate 1,928 mg/2 Ml	Nebuliser Suspension
Italy	Promedica S.R.L.	Clenil Compositum	Beclometasone Dipropionate 50 µg Actuation, Salbutamol Sulfate 120 µg Actuation	Pressurised Inhalation, Solution
Italy	Simesa S.P.A.	Assieme	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Simesa S.P.A.	Assieme	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Italy	Valeas S.P.A.	Plenaer	Flunisolide 25 mg Bottle, Salbutamol 10 mg Bottle	Pressurised Inhalation, Suspension
Italy	Valeas S.P.A.	Plenaer	Salbutamol Sulfate 0,602 mg Vial, Flunisolide 0,5 mg Vial	Nebuliser Solution
Latvia	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Latvia	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Latvia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Latvia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Latvia	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Latvia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Latvia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Latvia	Glaxosmithkline Latvia Sia	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Latvia	Glaxosmithkline Latvia Sia	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Latvia	Glaxosmithkline Latvia Sia	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Latvia	Glaxosmithkline Latvia Sia	Flosal	Fluticasone Propionate 250 µg Inhalation, Salmeterol Xinafoate 25 µg Inhalation	Pressurised Inhalation, Suspension
Latvia	Glaxosmithkline Latvia Sia	Flosal	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Latvia	Glaxosmithkline Latvia Sia	Seretide	Fluticasone Propionate 250 µg Inhalation, Salmeterol Xinafoate 25 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Latvia	Glaxosmithkline Latvia Sia	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Latvia	Novartis Finland Oy	Miflonide	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Latvia	Novartis Finland Oy	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Latvia	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Latvia	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Latvia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Latvia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Lithuania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Lithuania	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Lithuania	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Lithuania	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Glaxosmithkline Lietuva Uab	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Lithuania	Glaxosmithkline Lietuva Uab	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Glaxosmithkline Lietuva Uab	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Glaxosmithkline Lietuva Uab	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Novartis Finland Oy	Miflonide	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Lithuania	Novartis Finland Oy	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Lithuania	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Lithuania	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg, Formoterol Fumarate Dihydrate 4,5 µg	Inhalation Powder
Lithuania	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Lithuania	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg, Formoterol Fumarate Dihydrate 9 µg	Inhalation Powder
Lithuania	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Lithuania	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Luxembourg	Chiesi Sa-Nv	Inuvair	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Luxembourg	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Luxembourg	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Luxembourg	Nv Astrazeneca Sa	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Luxembourg	Nv Astrazeneca Sa	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Luxembourg	Nv Astrazeneca Sa	Symbicort Forte Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Malta	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Malta	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Malta	Astrazeneca Ab	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Malta	Astrazeneca Ab	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Malta	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Malta	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Malta	Glaxosmithkline (Ireland) Limited	Flixotide Evohaler	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Malta	Glaxosmithkline (Ireland) Limited	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Malta	Novartis Pharmaceuticals Uk Limited	Miflonide	Budesonide 200 µg Capsule	Inhalation Powder, Hard Capsule
Malta	Novartis Pharmaceuticals Uk Limited	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Malta	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Malta	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Malta	Orion Oyj	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Malta	Orion Oyj	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Netherlands	Astrazeneca Bv	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Netherlands	Astrazeneca Bv	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Netherlands	Glaxosmithkline B.V.	Fluticasonpropionaat Inhalator GSK	Fluticasone Propionate 125 µg Dose	Aerosol
Netherlands	Glaxosmithkline B.V.	Fluticasonpropionaat Inhalator GSK	Fluticasone Propionate 250 µg Dose	Aerosol
Netherlands	Glaxosmithkline B.V.	Fluticasonpropionaat Inhalator GSK	Fluticasone Propionate 50 µg Dose	Aerosol
Netherlands	Chiesi Pharmaceuticals B.V.	Formodual	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Netherlands	Chiesi Pharmaceuticals B.V.	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Netherlands	Elpen Pharmaceutical Co. Inc.	Salmeterol/Fluticasonpropionaat Elpen	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Netherlands	Elpen Pharmaceutical Co. Inc.	Salmeterol/Fluticason-propionaat Elpen	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Netherlands	Glaxosmithkline B.V.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Netherlands	Glaxosmithkline B.V.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Netherlands	Glaxosmithkline B.V.	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Norway	Astrazeneca As	Symbicort Forte Turbu-haler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Norway	Astrazeneca As	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Norway	Chiesi Farmaceutici S.P.A.	Inuxair	Beclometasone Dipropionate 100 µg Actuation, For-moterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Norway	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Norway	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Norway	Glaxosmithkline As	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Norway	Sandoz A-S	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone Propionate 250 µg Dose	Inhalation Powder
Norway	Sandoz A-S	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone Propionate 500 µg Dose	Inhalation Powder
Poland	Adamed Sp. Z O.O.	Flutixon	Fluticasone Propionate 125 µg Capsule	Inhalation Powder, Hard Capsule
Poland	Adamed Sp. Z O.O.	Flutixon	Fluticasone Propionate 250 µg Capsule	Inhalation Powder, Hard Capsule
Poland	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Poland	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Poland	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Poland	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Poland	Celon Pharma S.A.	Salmex	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Poland	Chiesi Pharmaceuticals Gmbh	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Poland	Chiesi Pharmaceuticals Gmbh	Fostex	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Poland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Glaxosmithkline Export Ltd	Flixotide	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Glaxosmithkline Export Ltd	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Poland	Glaxosmithkline Export Ltd	Flixotide Dysk	Fluticasone Propionate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Glaxosmithkline Export Ltd	Seretide Dysk	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Poland	Meda Pharma Gmbh & Co. Kg	Budelin Novolizer	Budesonide 200 µg Dose	Inhalation Powder
Poland	Novartis Poland Sp. Z O. O.	Miflonide	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Poland	Novartis Poland Sp. Z O. O.	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Poland	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Poland	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Poland	Polfarmex S.A.	Asaris	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Budezonid Lek-Am	Budesonide 200 µg Inhalation	Inhalation Powder, Hard Capsule
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Budezonid Lek-Am	Budesonide 400 µg Inhalation	Inhalation Powder, Hard Capsule
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Assieme Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Assieme Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmaceuticos Limitada	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmaceuticos Limitada	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Portugal	Bialfar — Produtos Farmacêuticos, Sociedade Anónima	Brisomax Diskus	Fluticasone Propionate 100 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Bialfar — Produtos Farmacêuticos, Sociedade Anónima	Brisomax Diskus	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Portugal	Bialfar — Produtos Farmacêuticos, Sociedade Anónima	Brisomax Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.	Budesonida Farmoz	Budesonide 200 µg Dose	Inhalation Powder
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.	Budesonida Farmoz	Budesonide 400 µg Dose	Inhalation Powder
Portugal	Glaxo Wellcome Farmacêutica, Limitada	Seretaide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Glaxosmithkline — Produtos Farmacêuticos, Limitada	Maizar Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Portugal	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Portugal	Pentafarma — Sociedade Tecnico-Medicinal S.A.	Budesonida Tecnicort	Budesonide 200 µg Dose	Inhalation Powder
Portugal	Pentafarma — Sociedade Tecnico-Medicinal S.A.	Budesonida Tecnicort	Budesonide 400 µg Dose	Inhalation Powder
Portugal	Sandoz Farmacêutica, Limitada	Airflusal Forspiro	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Sandoz Farmacêutica, Limitada	Airflusal Forspiro	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Romania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Romania	Chiesi Pharmaceuticals Gmbh	Foster	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Romania	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Glaxo Wellcome Ltd	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Romania	Glaxo Wellcome Ltd	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Romania	Glaxo Wellcome Ltd	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Romania	Glaxo Wellcome Ltd	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Medochemie Romania S.R.L.	Frenolyn	Budesonide, Micronised 200 µg Dose	Inhalation Powder
Romania	Medochemie Romania S.R.L.	Frenolyn	Budesonide, Micronised 400 µg Dose	Inhalation Powder
Romania	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Romania	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Romania	S.C. Sandoz S.R.L.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Pulmicort Turbohaler	Budesonide 100 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Slovakia	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Slovakia	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Glaxo Group Limited	Flixotide	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension
Slovakia	Glaxo Group Limited	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Slovakia	Glaxo Group Limited	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Slovakia	Glaxo Group Limited	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 50 µg Dose	Inhalation Powder
Slovakia	Meda Pharma Spol. S R.O.	Budelin Novolizer	Budesonide 200 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Slovakia	Novartis, S.R.O.	Miflonid	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Slovakia	Novartis, S.R.O.	Miflonid	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Slovakia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Slovakia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Slovenia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Slovenia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Slovenia	Chiesi Pharmaceuticals Gmbh	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Slovenia	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Slovenia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovenia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovenia	Glaxosmithkline D.O.O., Ljubljana	Flixotide	Fluticasone Propionate 250 µg Spray	Pressurised Inhalation, Suspension
Slovenia	Glaxosmithkline D.O.O., Ljubljana	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Airflusan Forspiro	Salmeterol 50 µg Dose, Fluticasone Propionate 500 µg Dose	Inhalation Powder
Slovenia	Meda Pharma Gmbh & Co. Kg	Budelin Novolizer	Budesonide 200 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Allen Farmaceutica, S.A.	Anasma Accuhaler	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 50 µg Dose, Salmeterol Xinafoate 25 µg Dose	Pressurised Inhalation, Suspension
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 25 µg Dose	Pressurised Inhalation, Suspension
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 125 µg Dose, Salmeterol Xinafoate 25 µg Dose	Pressurised Inhalation, Suspension
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 100 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Astrazeneca Farmacéutica Spain, S.A.	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Spain	Astrazeneca Farmacéutica Spain, S.A.	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Spain	Astrazeneca Farmacéutica Spain, S.A.	Pulmicort Turbuhaler	Budesonide 400 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Spain	Astrazeneca Farmacéutica Spain, S.A.	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Spain	Astrazeneca Farmacéutica Spain, S.A.	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Spain	Chiesi España, S.A.	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Spain	Chiesi España, S.A.	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Dose	Pressurised Inhalation, Solution
Spain	Glaxosmithkline S.A.	Brisair Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Glaxosmithkline S.A.	Brisair Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Glaxosmithkline S.A.	Flixotide	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flixotide Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flixotide Accuhaler	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flixotide Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flusonal	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Spain	Glaxosmithkline S.A.	Flusonal	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flusonal Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flusonal Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Inalacor	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Inalacor	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Inalacor Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Inalacor Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Inaladuo Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Glaxosmithkline S.A.	Seretide Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Laboratorio Tau, S.A.	Rilast Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Spain	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Spain	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Spain	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Spain	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Spain	Smithkline Beecham Farma S.A.	Trialona	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Spain	Smithkline Beecham Farma S.A.	Trialona	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation, Suspension
Spain	Smithkline Beecham Farma S.A.	Trialona Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Smithkline Beecham Farma S.A.	Trialona Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Gardette	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Gardette Forte	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Sweden	Chiesi Farmaceutici S.P.A.	Innovair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Sweden	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Sweden	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose, Lactose Monohydrate 24,677 mg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Flutide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Flutide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Viani Diskus Forte	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Hexal Ag	Salmeterol/Fluticasone Hexal	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Sweden	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Sweden	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Sweden	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Sweden	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Sweden	Sandoz A-S	Aesalfluca Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Sandoz A-S	Flaxxone Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Flaxxone Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Lastenol Forspiro	Fluticasone Propionate 500 Microgram, Salmeterol Xinafoate 50 Microgram	Inhalation Powder

Member State in EEA	Marketing authorisaton holder	Product name	Active substance + Strength	Pharmaceutical form
Sweden	Sandoz A-S	Molduo Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Salmetorol/Fluticasone Sandoz	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Setirenol	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Setirenol	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
United Kingdom	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
United Kingdom	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
United Kingdom	Chiesi Limited	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
United Kingdom	Chiesi Limited	Fostair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
United Kingdom	Glaxo Wellcome Ltd	Seretide	Fluticasone Propionate 100 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
United Kingdom	Glaxo Wellcome Ltd	Seretide	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
United Kingdom	Glaxo Wellcome Ltd	Seretide Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

ANNEX II

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

Member State EU/ EEA	Applicant/marketing authorisation holder	Name	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Bulgaria	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Croatia	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
France	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use

Member State EU/ EEA	Applicant/marketing authorisation holder	Name	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Ireland	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Italy	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
The Netherlands	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Poland	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use

Member State EU/ EEA	Applicant/marketing authorisation holder	Name	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Romania	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Slovenia	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
Spain	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use
United Kingdom	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre ≥ 5,5 $\log_2$	Emulsion for injection	Cattle	Subcutaneous use

ANNEX III

List of the names, pharmaceutical forms, strength of the medicinal products, routes of administration, Marketing Authorisation Holders in the Member States

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Cyprus	MEDA Pharmaceuticals S.A. 3, Evritanias Str. GR-15231 Chalandri-Attiki Greece	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Finland	MEDA Oy Vaisalantie 4 FIN-02130 Espoo Finland	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Finland	MEDA Oy Vaisalantie 4 FIN-02130 Espoo Finland	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
France	MEDA Pharma S.A.S. 25, Boulevard de l'Amiral Bruix F-75016 Paris France	Novantrone 10 mg/ 5 ml, solution à diluer pour perfusion	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
France	MEDA Pharma S.A.S. 25, Boulevard de l'Amiral Bruix F-75016 Paris France	Novantrone 20 mg/ 10 ml, solution à diluer pour perfusion	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
France	MEDA Pharma S.A.S. 25, Boulevard de l'Amiral Bruix F-75016 Paris France	Elsep 2 mg/ml, solution à diluer pour perfusion	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantron 10 mg/5 ml	2 mg/ml	Concentrate for solution for infusion or solution for intrapleural or intraperitoneal use	Intravenous use Intrapleural use Intraperitoneal use	10 mg/5 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantron 20 mg/10 ml	2 mg/ml	Concentrate for solution for infusion or solution for intrapleural or intraperitoneal use	Intravenous use Intrapleural use Intraperitoneal use	20 mg/10 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Ralenova 2 mg/ml	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Ralenova 2 mg/ml	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	MEDA Pharmaceuticals S.A. 3, Evritanias Str. GR-15231 Chalandri-Attiki Greece	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Iceland	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Iceland	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
Italy	MEDA Pharma S.p.A. Viale Brenta 18 IT-20139 Milano Italy	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
Italy	MEDA Pharma S.p.A. Viale Brenta 18 IT-20139 Milano Italy	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Norway	MEDA A/S Askerveien 61 NO-1384 Asker Norway	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
Romania	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Slovenia	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantrone	2 mg/ml	Concentrate for solution for injection/infusion	Intravenous use	20 mg/10 ml
Spain	MEDA Pharma S.A.U. Edificio Berlin — Parque Empresarial San Fernando, Avda Castilla 2, 2ª planta E-28830 SAN FERNANDO DE HENARES (MADRID) Spain	Novantrone 20 mg solución inyectable	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Sweden	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Sweden	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml