Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 December 2013 to 31 December 2013

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

(2014/C 29/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
20.12.2013	Nicardipine	See Annex I	See Annex I	6.1.2014
19.12.2013	Hydroxyethyl starch	See Annex II	See Annex II	20.12.2013
20.12.2013	Metoclopramide only containing products	See Annex III	See Annex III	6.1.2014
18.12.2013	Ergot derivatives - (dihydroergotoxine)	See Annex IV	See Annex IV	20.12.2013

— Suspension of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
18.12.2013	Ergot derivatives - (dihydroergotoxine)	See Annex IV	See Annex IV	20.12.2013

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

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State (in EEA)	Applicant	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Belgium		Astellas Pharma BV, Erasmus Park, Square Marie Curie 50, Building 5, 1st floor 1070 Brussels Belgium	Nicardipine hydrochloride	Rydene	1 mg/ml	Solution for injection	Intravenous use
Belgium	Magenta Pharma Consulting Ericapark 38 2403 EG Alphen aan den Rijn The Netherlands		Nicardipine hydrochloride	Nicardipine Aguettant	10 mg/10 ml	Solution for injection	Intravenous use
France		NOVARTIS PHARMA SAS 2-4, rue Lionel Terray 92500 Rueil-Malmaison FRANCE	nicardipine (chlorhydrate de)	LOXEN 10 mg/10 ml, solution injectable (I.V.)	10 mg/10 ml	Solution for injection	Intravenous use
France		LABORATOIRE AGUETTANT 1, rue Alexander Fleming 69007 Lyon FRANCE	nicardipine (chlorhydrate de)	NICARDIPINE AGUETTANT 10 mg/10 ml, solution injectable	10 mg/10 ml	Solution for injection	Intravenous use
France		ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon FRANCE	nicardipine (chlorhydrate de)	NICARDIPINE ARROW 10 mg/10 ml, solution injectable	10 mg/10 ml	Solution for injection	Intravenous use
Luxembourg		ASTELLAS PHARMA Square Marie Curie 50 1 Building 5 1070 Brussels Belgium	Nicardipine	Rydene	1 mg/ml (5 ml)	Solution for injection	Intravenous use

Member State (in EEA)	Applicant	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Spain		ASTELLAS PHARMA, S.A. Paseo del Club Deportivo, 1 bloque 14 28223 Pozuelo de Alarcón (Madrid)	Nicardipine hydrochloride	VASONASE 1 mg/ml solución para perfusión	1 mg/ml	Solution for infusion	Intravenous use
The Netherlands		Astellas Pharma B.V. Sylviusweg 62 2333 BE Leiden The Netherlands	nicardipine	Cardene IV	5 mg/5 ml	Concentrate for solution for infusion	Intravenous use
United Kingdom	Mercury Pharmaceuticals Limited No. 1 Croydon, 12-16 Addiscombe Road, Croydon, Surrey CR0 0XT, United Kingdom		Nicardipine hydrochloride	Nicardipine 10 mg/10 ml solution for injection	1 mg/1 ml	Solution for injection	Intravenous use

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	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium Chloride	HAES-steril 'Fresenius' (HES 200/0,5) 6 % - Infusionsloesung	60 g/l, 9 g/l	solution for infusion	intravenous use
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium Chloride	HyperHAES 6 % in 7,2 % NaCl – Infusionsloesung	60 g/l, 72 g/l	solution for infusion	intravenous use
Austria	Baxter Healthcare GmbH Stella-Klein-Loew-Weg 15 1020 Vienna Austria	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate	PlasmaHES Redibag – Infusionsloesung	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,200 g/l, 3,70 g/l	solution for infusion	intravenous use
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium Chloride	Refortan 6 % Infusionsflasche	60 g/l, 9 g/l	solution for infusion	intravenous use
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium Chloride	Refortan plus 10 % Infusionsflasche	100 g/l, 9 g/l	solution for infusion	intravenous use
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium Chloride	Stabisol 6 % Infusionsflasche	60 g/l, 9 g/l	solution for infusion	intravenous use
Austria	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan 100 mg/ml Infusionsloesung	100,0 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Austria	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan 60 mg/ml Infusionsloesung	60,0 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Austria	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium Chloride	VENOFUNDIN 60 mg/ml Infusionsloesung	60 g/l, 9 g/l	solution for infusion	intravenous use
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium acetate trihydrate, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate,	Volulyte 6 % Infusionsloesung	60,00 g/l, 4,63 g/l, 6,02 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use
Austria	Fresenius Kabi Austria GmbH Hafnerstraße 36 8055 Graz Austria	Hydroxyethyl Starch, Sodium Chloride	Voluven (HES 130/0,4) 6 % - Infusionsloesung	60 g/l, 9 g/l	solution for infusion	intravenous use
Belgium	Fresenius Kabi NV Molenberglei 7 2627 Schelle Belgium	Hydroxyethyl starch	Haes-Steril 10 %	100 mg/ml	solution for infusion	intravenous use
Belgium	Fresenius Kabi NV Molenberglei 7 2627 Schelle Belgium	Hydroxyethyl starch	Haes-Steril 6 %	60 mg/ml	solution for infusion	intravenous use
Belgium	Baxter SA Bd Rene Branquart, 80 7860 Lessines Belgium	Sodium Acetate (Trihydrate), Potassium Chlorid, Magnesium Chlorid Hexahydrate, Sodium Chlorid, Calcium Chlorid (Dihydrate), Hydroxyethyl starch	Plasmavolume Redibag 6 %	3,70 mg/ml, 0,40 mg/ml, 0,20 mg/ml, 6 mg/ml, 0,13 mg/ml, 60 mg/ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsugen Germany	Sodium Acetate (Trihydrate), Potassium Chlorid, Magnesium Chlorid Hexahydrate, Sodium Chlorid, Calcium Chlorid (Dihydrate), Hydroxyethyl starch, Malic Acid	Tetraspan 10 %	3,27 mg/ml, 0,30 mg/ml, 0,20 mg/ml, 6,25 mg/ml, 0,37 mg/ml, 100 mg/ml, 0,67 mg/ml	solution for infusion	intravenous use
Belgium	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsugen Germany	Sodium Acetate (Trihydrate), Potassium Chlorid, Magnesium Chlorid Hexahydrate, Sodium Chlorid, Calcium Chlorid (Dihydrate), Hydroxyethyl starch, Malic Acid	Tetraspan 6 %	3,27 mg/ml, 0,30 mg/ml, 0,20 mg/ml, 6,25 mg/ml, 0,37 mg/ml, 60 mg/ml, 0,67 mg/ml	solution for infusion	intravenous use
Belgium	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsugen Germany	Sodium Chlorid, Hydroxyethyl starch	Venohes 6 %	9 mg/ml, 60 mg/ml	solution for infusion	intravenous use
Belgium	Fresenius Kabi NV Molenberglei 7 2627 Schelle Belgium	Sodium Acetate (Trihydrate), Potassium Chlorid, Magnesium Chlorid Hexahydrate, Sodium Chlorid, Hydroxyethyl starch	Volulyte 6 %	4,63 mg/ml, 0,30 mg/ml, 0,30 mg/ml, 6,02 mg/ml, 60 mg/ml	solution for infusion	intravenous use
Belgium	Fresenius Kabi NV Molenberglei 7 2627 Schelle Belgium	Sodium Chlorid, Hydroxyethyl starch	Voluven 10 %	9 mg/ml, 100 mg/ml	solution for infusion	intravenous use
Belgium	Fresenius Kabi NV Molenberglei 7 2627 Schelle Belgium	Sodium Chlorid, Hydroxyethyl starch	Voluven 6 %	9 mg/ml, 60 mg/ml	solution for infusion	intravenous use
Bulgaria	B.Braun Melsungen AG Carl-Braun-Strasse 1 D-34212 Melsungen Germany	Poly(O-2-Hydroxyethyl) starch, Sodium chloride	Hemohes 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Poly(O-2-Hydroxyethyl) starch, Sodium chloride	Voluven 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Bulgaria	Fresenius Kabi EOOD 'Alexander Jendov' str. 1 6th floor, ap 37+Sofia 1113 Bulgaria	Poly(O-2-Hydroxyethyl) starch, Sodium chloride	Voluven 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Bulgaria	Fresenius Kabi EOOD 'Alexander Jendov' str. 1 6th floor, ap 37+Sofia 1113 Bulgaria	Poly(O-2-Hydroxyethyl) starch, Sodium chloride, Sodium acetate trihtdrate, Potassium chloride, Magnesium chloride hexahydrate	Volulyte 6 %	60 g/l, 6,02 g/l, 4,63 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Bulgaria	Baxter Deutschland GmbH, Edissonstrasse 4+Unterschleissheim, 85716 Germany	Hydroxyethyl Starch 130/0,42, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate	Plasma volume Redibag	60,0 g/l, 6 g/l, 0,400 g/l, 0,134 g/l, 0,2 g/l, 3,70 g/l	solution for infusion	intravenous use
Croatia	B. Braun Adria d.o.o Hondlova 2/9 10000 Zagreb Croatia	Calcium chloride dihydrate, hydroxyethyl starch (HES), potassium chloride, magnesium chloride hexahydrate, sodium chloride, sodium acetate trihydrate, malic acid	TETRASPAN 60 mg/ml SOLUTION FOR INFUSION	0,37 g/l, 60,0 g/l, 0,30 g/l, 0,2 g/l, 6,25 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Croatia	B. Braun Adria d.o.o Hondlova 2/9 10000 Zagreb Croatia	Calcium chloride dihydrate, hydroxyethyl starch (HES), potassium chloride, magnesium chloride hexahydrate, sodium chloride, sodium acetate trihydrate, malic acid	TETRASPAN 100 mg/ml SOLUTION FOR INFUSION	0,37 g/l, 100,0 g/l, 0,30 g/l, 0,2 g/l, 6,25 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Croatia	Fresenius Kabi d.o.o. Trg J.F. Kennedya 6b 10000 Zagreb Croatia	Hydroxyethyl starch, Sodium chloride, Sodium acetate trihydrate, Potassium chloride, Magnesium chloride hexahydrate	VOLULYTE 6 % SOLUTION FOR INFUSION	60,0 g/l, 6,02 g/l, 4,63 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Croatia	Fresenius Kabi d.o.o. Trg J.F. Kennedya 6b 10000 Zagreb Croatia	Hydroxyethyl starch, Sodium chloride	VOLUVEN 6 % SOLUTION FOR INFUSION	60,0 g/l, 9,0 g/l	solution for infusion	intravenous use
Cyprus	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl starch + Sodium chloride+Sodium acetate trihydrate+Potassium chloride+Magnesium chloride hexahydrate	VOLULYTE SOLUTION FOR INFUSION 6 %	60 g/l, 6,02 g/l, 4,63 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Cyprus	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl starch + Sodium chloride	VOLUVEN SOLUTION FOR INFUSION 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Czech Republic	BAXTER CZECH spol. S r.o. Karla Engliše 3201/6 150 00 Praha 5 Czech Republic	Hydroxyethyl Starch 130 000, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate	PLASMA VOLUME REDIBAG 6 %	60,0 g/l, 6,0 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Czech Republic	B. Braun Melsungen AG Carl-Braun Strasse 1 342 12 Melsungen Germany	Hydroxyethyl Starch 130 000, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate, L-Malic Acid	TETRASPAN 10 %	100,0 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Czech Republic	B. Braun Melsungen AG Carl-Braun Strasse 1 342 12 Melsungen Germany	Hydroxyethyl Starch 130 000, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate, L-Malic Acid	TETRASPAN 6 %	60,0 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Czech Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hetastarch, Sodium Acetate Trihydrate, Sodium Chloride, Potassium Chloride, Magnesium Chloride Hexahydrate	VOLULYTE 6 %	60,0 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Fresenius Kabi s.r.o. Zeletavská 1525/1 140 00 Praha 4 - Michle Czech Republic	Hetastarch, Sodium Chloride	VOLUVEN 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Czech Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hetastarch, Sodium Chloride	HYPERHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Czech Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hetastarch, Sodium Chloride	VOLUVEN	60 g/l, 9 g/l	solution for infusion	intravenous use
Denmark	Baxter A/S Gydevang 43 DK-3450 Allerød Denmark	Calcium chloride dihydrate, hydroxyethyl starch (hes), potassium chloride, magnesium chloride hexahydrate, sodiumchloride, sodium acetate trihydrate, water	Hesra	0,134 g/l, 60 g/l, 0,4 g/l, 0,2 g/l, 6 g/l, 3,7 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Denmark	Fresenius Kabi AB Rapsgatan 7 SE-751 74 Uppsala Sweden	Hydroxyethyl starch (HES), sodiumchloride, water	HyperHAES	60 g/l, 72 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Denmark	B. Braun Melsungen Carl-Braun-Strasse 1 DE-34212 Melsungen Germany	Calcium chloride dihydrate, hydroxyethyl starch (HES), potassium chloride, magnesium chloride hexahydrate, sodium chloride, sodium acetate trihydrate, malic acid, sodium hydroxide, water	Tetraspan	0,37 g/l, 60 g/l, 0,3 g/l, 0,2 g/l, 6,25 g/l, 3,27 g/l, 0,67 g/l, 1,197 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Denmark	B. Braun Melsungen Carl-Braun-Strasse 1 DE-34212 Melsungen Germany	Calcium chloride dihydrate, hydroxyethyl starch (HES), potassium chloride, magnesium chloride hexahydrate, sodium chloride, sodium acetate trihydrate, malic acid, sodium hydroxide, water	Tetraspan	0,37 g/l, 100 g/l, 0,3 g/l, 0,2 g/l, 6,25 g/l, 3,27 g/l, 0,67 g/l, 1,197 g/l, water ad 1 000 ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Denmark	B. Braun Melsungen Carl-Braun-Strasse 1 DE-34212 Melsungen Germany	Hydroxyethyl starch (HES), sodium chloride, water	Venofundin	60 g/l, 9 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Denmark	Fresenius Kabi AB Rapsgatan 7 SE-751 74 Uppsala Sweden	Hydroxyethyl starch (HES), potassium chloride, magnesium chloride hexahydrate, sodium chloride, sodium acetate trihydrate, water	Volulyte	60 g/l, 0,3 g/l, 0,3 g/l, 6,02 g/l, 4,63 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Denmark	Fresenius Kabi AB Rapsgatan 7 SE-751 74 Uppsala Sweden	Hydroxyethyl starch (HES), Sodium Chloride, water	Voluven	60 g/l, 9 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Denmark	Fresenius Kabi AB Rapsgatan 7 SE-751 74 Uppsala Sweden	Hydroxyethyl starch (HES), Sodium Chloride, water	Voluven	100 g/l, 9 g/l, water ad 1 000 ml	solution for infusion	intravenous use
Estonia	B.Braun Melsungen AG Carl-Braun-Strasse 1 Melsungen D-34212 Germany	Hydroxyethyl starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride, Sodium acetate trihydrate, Malic acid	TETRASPAN 60 MG/ML	60 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Estonia	B.Braun Melsungen AG Carl-Braun-Strasse 1 Melsungen D-34212 Germany	Hydroxyethyl starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride, Sodium acetate trihydrate, Malic acid	TETRASPAN 100 MG/ML	100 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Estonia	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl starch, Sodium chloride	VOLUVEN	60 g/l, 9 g/l	solution for infusion	intravenous use
Estonia	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl starch, Sodium acetate trihydrate, Sodium chloride, Sodium chloride, Magnesium chloride	VOLULYTE	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Estonia	Fresenius Kabi Polska Sp.z o.o Crown Tower ul.Hrubieszowska 2 Warszawa 01-209 Poland	Hydroxyethyl starch, Sodium chloride	VOLUFORTE	100 g/l, 9 g/l	solution for infusion	intravenous use
Finland	Baxter Oy Tammasaarenkatu 1 P.O.Box 119 00181 Helsinki, Finland	Poly(o-2-hydroxyethyl) Starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Dihydrate, Sodium Acetate Trihydride	HESRA	60,0 g/l, 6,000 g/l, 0,400 g/l, 0,134 g/l, 0,200 g/l, 3,700 g/l	solution for infusion	intravenous use
Finland	Fresenius Kabi Ab Rapsgatan 7 75174 Uppsala, Sweden	Poly(o-2-hydroxyethyl) Starch, Sodium Chloride	HYPERHAES	60,0 g/l, 72 g/l	solution for infusion	intravenous use
Finland	B. Braun Melsungen AG Carl-Braun-Strasse 1 34209 Melsungen, Germany	Poly(o-2-hydroxyethyl) Starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydride, Malic Acid	TETRASPAN	100,0 g/l, 6,252 g/l, 0,2984 g/l, 0,3675 g/l, 0,2033 g/l, 3,266 g/l, 0,671 g/l	solution for infusion	intravenous use
Finland	B. Braun Melsungen AG Carl-Braun-Strasse 1 34209 Melsungen, Germany	Poly(o-2-hydroxyethyl) Starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Dihydrate, Sodium Acetate Trihydride, Malic Acid	TETRASPAN	60,0 g/l, 6,252 g/l, 0,2984 g/l, 0,3675 g/l, 0,2033 g/l, 3,266 g/l, 0,671 g/l	solution for infusion	intravenous use
Finland	B. Braun Melsungen AG Carl-Braun-Strasse 1 34209 Melsungen, Germany	Poly(o-2-hydroxyethyl) Starch, Sodium Chloride	VENOFUNDIN	60,0 g/l, 9 g/l	solution for infusion	intravenous use
Finland	Fresenius Kabi Ab Rapsgatan 7 75174 Uppsala, Sweden	Poly(o-2-hydroxyethyl) Starch, Sodium Acetate Trihydride, Sodium Chloride, Potassium Chloride, Magnesium Chloride Hexahydrate	VOLULYTE	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Finland	Fresenius Kabi Ab Rapsgatan 7 75174 Uppsala, Sweden	Poly(o-2-hydroxyethyl) Starch, Sodium Chloride	VOLUVEN	60 g/l, 9,0 g/l	solution for infusion	intravenous use
Finland	Fresenius Kabi Ab Rapsgatan 7 75174 Uppsala, Sweden	Hydroxyethyl Starch, Sodium Chloride	VOLUVEN	100 g/l, 9,0 g/l	solution for infusion	intravenous use
France	B BRAUN MELSUNGEN Carl-Braun Strasse 1 34212 Melsungen Germany	hydroxyethyl starch 130 000 calcium chloride dihydrate magnesium chloride hexahydrate malic acide potassium chloride sodium acetate trihydrate sodium chloride	ISOVOL 6 %, solution pour perfusion	60 g / l 0,367 g / l 0,203 g / l 0,671 g / l 0,298 g / l 3,266 g / l 6,252 g / l	solution for infusion	intravenous use
France	BAXTER S.A.S. Avenue Louis Pasteur ZA de Coignères Maurepas 78310 Maurepas France	hydroxyethyl starch 130 000 calcium chloride dihydrate magnésium chloride hexahydrate potassium chloride sodium acetate trihydrate sodium chloride	PLASMAVOLUME 6 %, solution pour perfusion	60 g / l 0,134 g / l 0,2 g / l 0,4 g / l 3,7 g / l 6 g / l	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE 5, place du Marivel 92316 Sèvres Cedex France	hydroxyethyl starch 130 000 magnesium chloride hexahydrate potassium chloride sodium acetate trihydrate sodium chloride	VOLULYTE 6 %, solution pour perfusion	60 g / l 0,3 g / l 0,3 g / l 4,63 g / l 6,02 g / l	solution for infusion	intravenous use
France	B BRAUN MELSUNGEN Carl-Braun Strasse 1 34212 Melsungen Germany	hydroxyethyl starch 130 000 sodium chloride	RESTORVOL 6 %, solution pour perfusion	60 g / l 9 g / l	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 130 000 sodium chloride	VOLUVEN, solution pour perfusion	60 g / l 9 g / l	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 200 000	ELOHES 6 %, solution pour perfusion en poche	6 g / 100 ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 200 000	ELOHES 6 %, solution injectable pour perfusion en flacon	6 g / 100 ml	solution for infusion	intravenous use
France	AGUETTANT 1, rue Alexander Fleming 69007 Lyon France	hydroxyethyl starch 200 000	PLASMOHES 6 %, solution pour perfusion	6 g / 100 ml	solution for infusion	intravenous use
France	B BRAUN MELSUNGEN Carl-Braun Strasse 1 34212 Melsungen Germany	hydroxyethyl starch 200 000 sodium chloride	HEAFUSINE 10 %, solution pour perfusion en poche	10 g / 100 ml 0,90 g / 100 ml	solution for infusion	intravenous use
France	B BRAUN MELSUNGEN Carl-Braun Strasse 1 34212 Melsungen Germany	hydroxyethyl starch 200 000 sodium chloride	HEAFUSINE 6 %, solution pour perfusion en poche	6 g / 100 ml 0,90 g / 100 ml	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 200 000 sodium chloride	HYPERHES, solution pour perfusion	60 g / l 72 g / l	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 240 000	HESTERIL 10 %, solution pour perfusion	10 g / 100 ml	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 240 000	HESTERIL 6 %, solution pour perfusion	6 g / 100 ml	solution for infusion	intravenous use
France	FRESENIUS KABI FRANCE Place du Marivel 5 92316 Sèvres Cedex France	hydroxyethyl starch 250 000	LOMOL, solution injectable pour perfusion en poche	10 g / 100 ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Germany	B. Braun Melsungen AG Carl-Braun-Str. 1 34212 Melsungen Germany	Hydroxyethyl starch Sodium Chloride	Hemohes 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Germany	B. Braun Melsungen AG Carl-Braun-Str. 1 34212 Melsungen Germany	Hydroxyethyl starch Sodium Chloride	Hemohes 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Germany	B. Braun Melsungen AG Carl-Braun-Str. 1 34212 Melsungen Germany	Hydroxyethyl starch Sodium Chloride	VENOFUNDIN 60 mg/ml Infusionslösung	60 g/l, 9 g/l	solution for infusion	intravenous use
Germany	B. Braun Melsungen AG Carl-Braun-Str. 1 34212 Melsungen Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate, Malic Acid	Tetraspan 6 % Infusionslösung	60 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Germany	B. Braun Melsungen AG Carl-Braun-Str. 1 34212 Melsungen Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate, Malic Acid	Tetraspan 10 % Infusionslösung	100 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Germany	Baxter Deutschland GmbH Edisonstr. 4 85716 Unterschleißheim Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate	Plasma Volume Redibag	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Sodium Chloride, Hydroxyethyl starch	Refortan 6 %	9 g/l, 60 g/l	solution for infusion	intravenous use
Germany	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Sodium Chloride, Hydroxyethyl starch	Refortan 10 %	9 g/l, 100 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Acetate Trihydrate, Sodium Chloride, Potassium Chloride, Magnesium Chloride Hexahydrate	Volulyte 6 % Infusionslösung	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	Voluven 6 % Infusionslösung	9 g/l, 60 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	Voluven 10 % Infusionslösung	9 g/l, 100 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	Elohäst 6 %	9 g/l, 60 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	HyperHAES Infusionslösung	72 g/l, 60 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	HAES-steril 3 %	9 g/l, 30 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	Voluven Fresenius 6 % Infusionslösung	9 g/l, 60 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Sodium Chloride, Hydroxyethyl starch	Haes-steril 10 %	9 g/l, 100 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Acetate Trihydrate, Sodium Chloride, Potassium Chloride, Magnesium Chloride Hexahydrate	Volulyte 6 % Infusionslösung	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Chloride	Haes-steril 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Chloride	Voluven 6 % Infusionslösung	60 g/l, 9 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Chloride	Voluven 10 % Infusionslösung	100 g/l, 9 g/l	solution for infusion	intravenous use
Germany	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Chloride	HyperHAES Infusionslösung	60 g/l, 72 g/l	solution for infusion	intravenous use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride	Infukoll HES 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate	Vitafusal 10 %	100 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate	Vitakoll 10 %	100 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride	Infukoll HES 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate	Vitafusal 6 %	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate Sodium Acetate Trihydrate	Vitafusal	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Germany	Serumwerk Bernburg AG Hallesche Landstr. 105b 06406 Bernburg Germany	Hydroxyethyl starch, Sodium Chloride	VitaHES Infusionslösung	60 g/l, 9 g/l	solution for infusion	intravenous use
Greece	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Poly-(o-2 hydroxyethyl)-starch (M.W 200 000) + Sodium Chloride	HAES-STERIL	60 g/l + 9 g/l	solution for infusion	intravenous use
Greece	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl Starch + Sodium Chloride	VOLUVEN	60 g/l + 9 g/l	solution for infusion	intravenous use
Greece	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl Starch + Sodium Chloride	VOLUVEN	100 g/l + 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Greece	VIOSER SA, 9th Km National Highway Trikala-Larissis, P.O. Box 35, Taxiarhes, Trikala, Trikala 42100 Greece	Hydroxyethyl Starch + Sodium Chloride	VENOFUNDIN	60 g/l + 9 g/l	solution for infusion	intravenous use
Greece	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Poly-(o-2-hydroxyethyl)-starch (M.W 200 000) + sodium acetate trihydrate + sodium chloride + potassium chloride + magnesium chloride hexahydrate	VOLULYTE	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Greece	BAXTER HELLAS Ltd, Metsovou 3, Neo Irakleion 14121, Athens Greece	Hydroxyethyl starch + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate + Magnesium Chloride Hexahydrate + Sodium Acetate Trihydrate	PLASMAVOLUME REDIBAG	60 g/l + 6 g/l + 0,4 g/l + 0,134 g/l + 0,2 g/l + 3,7 g/l	solution for infusion	intravenous use
Greece	VIOSER SA 9th Km National Highway Trikal-Larissa, P.O. Box 35, Taksiarhes Trikalon, Trikala 42100 Greece	Poly(o-2-hydroxyethyl)starch (M.W 200 000) + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate + Magnesium Chloride Hexahydrate + Sodium Acetate Trihydrate + Malic Acid	TETRASPAN	60 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Greece	VIOSER SA 9th Km National Highway Trikal-Larissa, P.O. Box 35, Taksiarhes Trikalon, Trikala 42100 Greece	Poly-(o-2-hydroxyethyl)-starch (MW 200 000) + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate + Magnesium Chloride Hexahydrate + Sodium Acetate Trihydrate + Malic Acid	TETRASPAN	100 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Hungary	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium chloride	VOLUVEN 10 % oldatos infúzió	100 g/l, 9,0 g/l	solution for infusion	intravenous use
Hungary	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium chloride	VOLUVEN 6 % oldatos infúzió	60,0 g/l, 9,0 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Hungary	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium chloride	HAES-STERIL 10 % oldatos infúzió	100 g/l, 9 g/l	solution for infusion	intravenous use
Hungary	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium chloride	HYPERHAES oldatos infúzió	101 g/l, 9 g/l	solution for infusion	intravenous use
Hungary	B.Braun Melsungen AG Carl Braun Strasse 1 Melsungen Germany	HES, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate, Malic Acid	Tetraspan 60 mg/ml	60 g/l, 6,252 g/l, 0,2984 g/l, 0,3675 g/l, 0,2033 g/l, 3,266 g/l, 0,67 g/l	solution for infusion	intravenous use
Hungary	B.Braun Melsungen AG Carl Braun Strasse 1 Melsungen Germany	HES, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate, Malic Acid	Tetraspan 100 mg/ml	100 g/l, 6,252 g/l, 0,2984 g/l, 0,3675 g/l, 0,2033 g/l, 3,266 g/l, 0,67 g/l	solution for infusion	intravenous use
Hungary	Baxter Hungary Kft Népfürdő u. 22. Budapest H-1138 Hungary	HES, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate	HesRa	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Iceland	Fresenius Kabi AB Rapsgatan 7 751 74 Uppsala Sweden	Hydroxyethy starch, Sodium chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Iceland	B.Braun Melsungen AG Carl Braun Strasse 1 Melsungen Germany	Hydroxyethyl starch, Sodium chloride, potassium chloride, calcium chloride, magnesium chloride, sodium acetat, malic acid	Tetraspan	60 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Iceland	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl starch, sodium acetat, sodium chloride, potassium chloride, magnesium chloride	Volulyte	60 g/l, 4,63 g/l, 6,02 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Iceland	Fresenius Kabi AB Rapsgatan 7 751 74 Uppsala Sweden	Hydroxyethyl starch, sodium chloride	Voluven	60 g/l, 9,0 g/l	solution for infusion	intravenous use
Ireland	Baxter Healthcare Limited Caxton Way Thetford Norfolk IP24 3SE United Kingdom	Hydroxyethyl Starch, Sodium Chloride, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate, Sodium Acetate Trihydrate	Plasma Volume Redibag 6 % Solution for Infusion	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,200 g/l, 3,7 g/l	solution for infusion	intravenous use
Ireland	B. Braun Melsungen AG, Harald Weis, Carl-Braun Strasse 1, 34212 Melsungen, Germany	Poly (O-2-hydroxyethyl) starch (HES) Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, L-Malic acid DAB	EquiHes 60 mg/ml solution for infusion, Ecoflac Plus	60 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Ireland	B. Braun Melsungen AG, Harald Weis, Carl-Braun Strasse 1, 34212 Melsungen, Germany	Poly (O-2-hydroxyethyl) starch (HES), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid DAB	EquiHes 100 mg/ml solution for infusion, Ecoflac Plus	100 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Ireland	B. Braun Melsungen AG, Harald Weis, Carl-Braun Strasse 1, 34212 Melsungen, Germany	Poly (O-2-hydroxyethyl) starch (HES), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid DAB	EquiHes 60 mg/ml solution for infusion, Ecobag	60 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Ireland	B. Braun Melsungen AG, Harald Weis, Carl-Braun Strasse 1, 34212 Melsungen, Germany	Poly (O-2-hydroxyethyl) starch (HES), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid DAB	EquiHes 100 mg/ml solution for infusion, Ecobag	100 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (0-2-hydroxyethyl)starch sodium chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (0-2-hydroxyethyl)starch sodium chloride	Voluven 10 % Solution for Infusion (Polyolefine Bag)	100 g/l 9 g/l	solution for infusion	intravenous use
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (o-2-hydroxyethyl)starch sodium chloride	Voluven 10 % Solution for Infusion (PE Bottle)	100 g/l 9,00 g/l	solution for infusion	intravenous use
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (o-2-hydroxyethyl)starch sodium chloride	Voluven 6 % Solution for Infusion (Glass bottle)	60 g/l 9 g/l	solution for infusion	intravenous use
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (o-2-hydroxyethyl)starch sodium chloride	Voluven 6 % Solution for Infusion (Polyolefine/Freeflex Bag	60 g/l 9 g/l	solution for infusion	intravenous use
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (o-2-hydroxyethyl)starch sodium chloride	Voluven 6 % Solution for Infusion (PVC Bag)	60 g/l 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly(o-2-hydroxyethyl)starch sodium acetate trihydrate sodium chloride potassium chloride magnesium chloride hexahydrate	Volulyte 6 % Solution for Infusion, polyoelfine bags	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly(o-2-hydroxyethyl)starch sodium acetate trihydrate sodium chloride potassium chloride magnesium chloride hexahydrate	Volulyte 6 % Solution for Infusion, glass bottle	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l	solution for infusion	intravenous use
Italy	FRESENIUS KABI ITALIA Srl Via Camagre, 41-43 Isola della Scala (Verona) 37063 Italy	Hydroxyethyl starch, Sodium Chloride	Vonten	100 g/l, 9 g/l	solution for infusion	intravenous use
Italy	FRESENIUS KABI ITALIA Srl Via Camagre, 41-43 Isola della Scala (Verona) 37063 Italy	Hydroxyethyl starch, Sodium Chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Italy	FRESENIUS KABI ITALIA Srl Via Camagre, 41-43 Isola della Scala (Verona) 37063 Italy	Hydroxyethyl starch, Sodium Chloride	Voluven	60 g/l, 9 g/l	solution for infusion	intravenous use
Italy	B. Braun Melsungen AG Carl-Braun-Straße 1 34209 Melsungen Germany	Hydroxyethyl starch, Sodium Chloride	Amidolite	60 g/l, 9 g/l	solution for infusion	intravenous use
Italy	B. Braun Melsungen AG Carl-Braun-Straße 1 34209 Melsungen Germany	Hydroxyethyl starch, Sodium Chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan	60 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Italy	B. Braun Melsungen AG Carl-Braun-Straße 1 34209 Melsungen Germany	Hydroxyethyl starch, Sodium Chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan	100 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Italy	Baxter S.p.A. Piazzale dell industria, 20 00144 Rome Italy	Hydroxyethyl starch, Sodium Chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate	Plasmavolume	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Italy	FRESENIUS KABI ITALIA Srl Via Camagre, 41-43 Isola della Scala (Verona) 37063 Italy	Hydroxyethyl starch, Sodium Chloride, Potassium chloride, Magnesium chloride hexahydrate, Sodium acetate trihydrate	Volulyte	60 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l, 4,63 g/l	solution for infusion	intravenous use
Italy	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Chloride	HAES-STERIL	60 g/l, 9 g/l	solution for infusion	intravenous use
Italy	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl starch, Sodium Chloride	HAES-STERIL	100 g/l, 9 g/l	solution for infusion	intravenous use
Latvia	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(O-2-hydroxyethyl)starch, Sodium chloride	Voluven 6 % solution for infusion	60 g, 9 g	solution for infusion	intravenous use
Latvia	Fresenius Kabi Polska Sp.z.o.o. Ul. Hrubieszowska 2 01-209 Warszawa Poland	Poly(O-2-hydroxyethyl)starch, Sodium chloride	Voluforte solution for infusion	100 g, 9 g	solution for infusion	intravenous use
Latvia	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(O-2-hydroxyethyl)starch, Sodium acetate trihydrate, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate	Volulyte 6 % solution for infusion	60 g, 4,63 g, 6,02 g, 0,30 g, 0,30 g	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Latvia	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Poly(O-2-hydroxyethyl) starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan 60 mg/ml solution for infusion	60 g, 6,25 g, 0,30 g, 0,37 g, 0,20 g, 3,27 g, 0,67 g	solution for infusion	intravenous use
Latvia	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Poly(O-2-hydroxyethyl) starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan 100 mg/ml solution for infusion	100 g, 6,25 g, 0,30 g, 0,37 g, 0,20 g, 3,27 g, 0,67 g	solution for infusion	intravenous use
Lithuania	UAB 'BERLIN CHEMIE MENARINI BALTIC' Jasinskio 16a, LT-01112 Vilnius, Lithuania	Hydroxyethyl starch	Refortan	60 g/l	solution for infusion	intravenous use
Lithuania	UAB 'BERLIN CHEMIE MENARINI BALTIC' Jasinskio 16a, LT-01112 Vilnius, Lithuania	Hydroxyethyl starch	Refortan Plus	100 g/l	solution for infusion	intravenous use
Lithuania	UAB 'BERLIN CHEMIE MENARINI BALTIC' Jasinskio 16a, LT-01112 Vilnius, Lithuania	Hydroxyethyl starch	Stabisol	60 g/l	solution for infusion	intravenous use
Lithuania	Fresenius Kabi Polska Sp.zo.o. ul.Hrubieszowska 2 01-209 Warszawa, Poland	Poli(O-2-hydroxyethyl) starch, Sodium chloride	Voluforte	100 g + 9 g/l	solution for infusion	intravenous use
Lithuania	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poli(O-2-hydroxyethyl) starch	Volulyte	60 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Lithuania	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poli(O-2-hydroxyethyl) starch, Sodium chloride	Voluven	60 g + 9 g/l	solution for infusion	intravenous use
Lithuania	B. Braun Melsungen AG Carl-Braun-strasse 1 34212 Melsungen Germany	Poli(0-2-hydroxyethyl)starch(HEK), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride heksahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan	60 g + 6,25 g + 0,3 g + 0,37 g + 0,2 g + 3,27 g + 0,67 g/l	solution for infusion	intravenous use
Lithuania	B. Braun Melsungen AG Carl-Braun-strasse 1 34212 Melsungen Germany	Poli(0-2-hydroxyethyl)starch(HEK), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride heksahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan	100 g + 6,25 g + 0,3 g + 0,37 g + 0,2 g + 3,27 g + 0,67 g/l	solution for infusion	intravenous use
Luxembourg	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(0-2-hydroxyethyl)starch 200 kDa mol.substitution 0,43-0,55, Sodium chloride	Haes-steril 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Luxembourg	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(0-2-hydroxyethyl)starch 200 kDa mol.substitution 0,43-0,55, Sodium chloride	Haes-steril 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Luxembourg	B.Braun Melsungen A.G. Carl-Braun-Straße 1 D-34212 Melsungen Germany	Poly(0-2-hydroxyethyl)starch 200 kDa mol.substitution 0,45-0,55, Sodium chloride	Hemohes 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Luxembourg	B.Braun Melsungen A.G. Carl-Braun-Straße 1 D-34212 Melsungen Germany	Poly(0-2-hydroxyethyl)starch 200 kDa mol.substitution 0,45-0,55, Sodium chloride	Hemohes 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Luxembourg	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(0-2-hydroxyethyl)starch 200 kDa mol.substitution 0,43-0,55, Sodium chloride	Hyperhaes	60 g/l, 72 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Baxter S.A. Boulevard René Branquart 80 B-7860 Lessines Belgium	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,42, Sodium chloride, Potassium chloride, Calcium chloride trihydrate, Magnesium chloride hexahydrate, sodium acetate trihydrate	Plasma Volume Redibag 6 %	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l	solution for infusion	intravenous use
Luxembourg	B.Braun Melsungen A.G. Carl-Braun-Straße 1 D-34212 Melsungen Germany	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,42, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, sodium acetate trihydrate, malic acid	Tetraspan 6 %	60 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Luxembourg	B.Braun Melsungen A.G. Carl-Braun-Straße 1 D-34212 Melsungen Germany	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,42, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, sodium acetate trihydrate, malic acid	Tetraspan 10 %	100 g/l, 6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Luxembourg	B.Braun Melsungen A.G. Carl-Braun-Straße 1 D-34212 Melsungen Germany	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,42, Sodium chloride	Venofundin 60 mg/ml	60 g/l, 9 g/l	solution for infusion	intravenous use
Luxembourg	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,38-0,45, Sodium acetate trihydrate, sodium chloride, potassium chloride, magnesium chloride hexahydrate	Volulyte 6 %	60 g/l, 4,63 g/l, 6,02 g/l, 0,3 g/l 0,3 g/l	solution for infusion	intravenous use
Luxembourg	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,38-0,45, Sodium chloride	Voluven 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use
Luxembourg	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(0-2-hydroxyethyl)starch 130 kDa mol.substitution 0,38-0,45, Sodium chloride	Voluven 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Malta	Fresenius Kabi Limited Cestrian Court Eastgate Way Manor Park Runcorn Cheshire WA7 1NT United Kingdom	Sodium acetate trihydrate, sodium chloride, potassium chloride, magnesium chloride hexahydrate, hydroxyethyl starch 130/0.4	Volulyte 6 % solution for infusion	4,63 g/l, 6,02 g/l. 0,3 g/l, 0,3 g/l, 60 g/l	solution for infusion	intravenous use
Malta	Baxter Healthcare Limited Caxton Way Thetford Norfolk IP24 3SE United Kingdom	Poly (O-2-hydroxyethyl starch (HES), sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate	Plasma Volume Redibag 6 % solution for infusion	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,200 g/l, 3,7 g/l	solution for infusion	intravenous use
Norway	Baxter AS Gjerdumsvei 11 0484 Oslo Norway	Poly(O-2-hydroxyethyl) starch (HES), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate	Hesra	60 g/l, 6,00 g/l, 0,400 g/l, 0,134 g/l, 0,200 g/l, 3,70 g/l	solution for infusion	intravenous use
Norway	Fresenius Kabi Norge AS Postboks 430 1753 Halden Norway	Poly(O-2-hydroxyethyl) starch (HES), Sodium chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Norway	B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany	Poly(O-2-hydroxyethyl) starch (HES), Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan	60 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3, 27 g/l, 0,67 g/l	solution for infusion	intravenous use
Norway	B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany	Poly(O-2-hydroxyethyl) starch (HES), Sodium chloride	Venofundin	60 g/l, 9 g/l	solution for infusion	intravenous use
Norway	Fresenius Kabi Norge AS Postboks 430 1753 Halden Norway	Poly(O-2-hydroxyethyl) starch (HES), Sodium acetate trihydrate, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate	Volulyte	60 g/l, 4,63 g/l, 6,02 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Fresenius Kabi Norge AS Postboks 430 1753 Halden Norway	Poly(O-2-hydroxyethyl) starch (HES), Sodium chloride	Voluven	100 g/l, 9 g/l	solution for infusion	intravenous use
Norway	Fresenius Kabi Norge AS Postboks 430 1753 Halden Norway	Poly(O-2-hydroxyethyl) starch (HES), Sodium chloride	Voluven	60 g/l, 9 g/l	solution for infusion	intravenous use
Poland	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl Starch	HAES - steril 10 %	100 g/l	solution for infusion	intravenous use
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Hydroxyethyl Starch, Sodium chloride	Refortan	60 g/l 9 g/l	solution for infusion	intravenous use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Hydroxyethyl Starch,	6 % Hydroksyetyloskrobia 200/0,5 Baxter	60 g/l	solution for infusion	intravenous use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Hydroxyethyl Starch	10 % Hydroksyetyloskrobia 200/0,5 Baxter	100 g/l	solution for infusion	intravenous use
Poland	Berlin-Chemie AG Glienicker Weg 125 12489 Berlin Germany	Hydroxyethyl Starch, Sodium chloride	Refortan Forte	100 g/l 9 g/l	solution for infusion	intravenous use
Poland	B. Braun Melsungen AG Carl-Braun Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride	Hemohes 6 %	60 g/l 9 g/l	solution for infusion	intravenous use
Poland	B. Braun Melsungen AG Carl-Braun Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride	Hemohes 10 %	100 g/l 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Poland	B. Braun Melsungen AG Carl-Braun Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Hydrated calcemia chloride, Hydrated magnesium chloride, Hydrated sodium acetate, Hydroxy succinic acid	Tetraspan 60 mg/ml HES roztwór do infuzji	60 g/l 6,25 g/l 0,30 g/l 0,37 g/l 0,20 g/l 3,27 g/l 0,67 g/l	solution for infusion	intravenous use
Poland	B. Braun Melsungen AG Carl-Braun Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Hydrated calcemia cloride, Hydrated magnesium chloride, Hydrated sodium acetate, Hydroxy succinic acid	Tetraspan 100 mg/ml HES roztwór do infuzji	100 g/l 6,252 g/l 0,2984 g/l 0,3675 g/l 0,2033 g/l 3,266 g/l 0,6710 g/l	solution for infusion	intravenous use
Poland	Baxter Polska Sp. z o.o. ul. Kruczkowskiego 8 00-380 Warszawa Poland	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Hydrated calcemia cloride, Hydrated magnesium chloride, Hydrated sodium acetate	PlasmaVolume Redibag	60 g/l 6,0 g/l 0,4 g/l 0,134 g/l 0,2 g/l 3,70 g/l	solution for infusion	intravenous use
Poland	Fresenius Kabi Polska Sp. z o.o. ul. Hrubieszowska 2 01-209 Warszawa Poland	Hydroxyethyl Starch, Sodium chloride	Voluven 10 %	100 g/l 9 g/l	solution for infusion	intravenous use
Poland	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Polyhydroxyethylstarch, Sodium chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Poland	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl Starch, Sodium chloride	VOLUVEN	60 g/l 9 g/l	solution for infusion	intravenous use
Poland	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Poly(O-2-hydoxyethyl)starch 130/0.4, Sodium chloride, Sodium acetate trihydrate, Potassium chloride, Magnesium chloride hexahydrate	Volulyte 6 %	60 g/l, 6,02 g/l, 4,63 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use
Portugal	Fresenius Kabi Pharma Portugal, Lda Av. do Forte, 3 Edifício Suécia III - Piso 2 2790-073 Carnaxide Portugal	Hydroxyethyl starch + Sodium chloride	Haes-Steril 10 %	100 mg/ml + 9 mg/ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Fresenius Kabi Pharma Portugal, Lda Av. do Forte, 3 Edifício Suécia III - Piso 2 2790-073 Carnaxide Portugal	Hydroxyethyl starch + Sodium chloride	Haes-Steril 6 %	60 mg/ml + 9 mg/ml	solution for infusion	intravenous use
Portugal	Fresenius Kabi Pharma Portugal, Lda Av. do Forte, 3 Edifício Suécia III - Piso 2 2790-073 Carnaxide Portugal	Hydroxyethyl starch + Sodium chloride	Voluven Fresenius	60 mg/ml + 9 mg/ml	solution for infusion	intravenous use
Portugal	Fresenius Kabi Pharma Portugal, Lda Av. do Forte, 3 Edifício Suécia III - Piso 2 2790-073 Carnaxide Portugal	Hydroxyethyl starch + Sodium chloride	HyperHAES	60 mg/ml + 72 mg/ml	solution for infusion	intravenous use
Portugal	B. Braun Melsungen A.G. Carl-Braun Strasse, 1 D-34212 Melsungen Germany	Hydroxyethyl starch + Sodium chloride	Venofundin	60 mg/ml + 9 mg/ml	solution for infusion	intravenous use
Portugal	Fresenius Kabi Pharma Portugal, Lda Av. do Forte, 3 Edifício Suécia III - Piso 2 2790-073 Carnaxide Portugal	Potassium chloride + Sodium acetate trihydrate + Magnesium chloride hexahydrate + Hydroxyethyl starch + Sodium chloride	Volulyte	0,3 mg/ml + 4,63 mg/ml + 0,3 mg/ml + 60 mg/ml + 6,02 mg/ml	solution for infusion	intravenous use
Portugal	B. Braun Melsungen A.G. Carl-Braun Strasse, 1 D-34212 Melsungen Germany	Potassium chloride + Sodium acetate trihydrate + Malic acid + Magnesium chloride hexahydrate + Sodium chloride + Hydroxyethyl starch + Calcium chloride dihydrate	Tetraspan	0,3 mg/ml + 3,27 mg/ml + 0,67 mg/ml + 0,2 mg/ml + 6,25 mg/ml + 60 mg/ml + 0,37 mg/ml	solution for infusion	intravenous use
Portugal	B. Braun Melsungen A.G. Carl-Braun Strasse, 1 D-34212 Melsungen Germany	Potassium chloride + Sodium acetate trihydrate + Malic acid + Magnesium chloride hexahydrate + Sodium chloride + Hydroxyethyl starch + Calcium chloride dihydrate	Tetraspan	0,3 mg/ml + 3,27 mg/ml + 0,67 mg/ml + 0,2 mg/ml + 6,25 mg/ml + 100 mg/ml + 0,37 mg/ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Baxter Médico-Farmacêutica, Lda. Zona Industrial da Abrunheira - Edifício 10 - Sintra Business Park 2710-089 Sintra Portugal	Sodium acetate trihydrate + Potassium chloride + Magnesium chloride hexahydrate + Hydroxyethyl starch + Calcium chloride dihydrate + Sodium chloride	PlasmaVolume Redibag	3,7 mg/ml + 0,4 mg/ml + 0,2 mg/ml + 60 mg/ml + 0,134 mg/ml + 6 mg/ml	solution for infusion	intravenous use
Portugal	Fresenius Kabi Pharma Portugal, Lda Av. do Forte, 3 Edifício Suécia III - Piso 2 2790-073 Carnaxide Portugal	Hydroxyethyl starch + Sodium chloride	Voluven Fresenius	100 mg/ml + 9 mg/ml	solution for infusion	intravenous use
Romania	S.C. INFOMED FLUIDS S.R.L., B-dul Theodor Pallady nr. 50, sector 3, București, 032266 Romania	Hydroxyethyl starch Sodium chloride Potassium chloride Calcium chloride dihydrate Magnesium chloride hexahydrate Sodium acetate trihydrate	VITAFUSAL	60 g/l, 6 g/l, 0,40 g/l, 0,134 g/l, 0,20 g/l, 3,70 g/l	solution for infusion	intravenous use
Romania	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl starch Sodium chloride	Voluven 60 g/1 000 ml	60 g/l, 9 g/l	solution for infusion	intravenous use
Romania	S.C. FRESENIUS KABI ROMÂNIA S.R.L. Strada Fânarului nr. 2A, 500464 Brașov, Romania	Hydroxyethyl starch Sodium chloride	VOLUVEN 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Romania	S.C. INFOMED FLUIDS S.R.L. B-dul Theodor Pallady nr. 50, sector 3, București, 032266 Romania	Hydroxyethyl starch Sodium chloride	INFOHES 60 g/L	60 g/l, 9 g/l	solution for infusion	intravenous use
Romania	S.C. INFOMED FLUIDS S.R.L. B-dul Theodor Pallady nr. 50, sector 3, București, Romania	Hydroxyethyl starch Sodium chloride	INFOHES 100 g/L	100 g/l, 9 g/l	solution for infusion	intravenous use
Romania	B. BRAUN MELSUNGEN AG Carl – Braun str. 1, D – 34212 Melsungen, Germany	Hydroxyethyl starch Sodium chloride	HEMOHES 6 %	60 g/l, 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Romania	B. BRAUN MELSUNGEN AG Carl – Braun str. 1, D – 34212 Melsungen, Germany	Hydroxyethyl starch Sodium chloride	HEMOHES 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Romania	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl starch Sodium chloride	HAES-steril 60 g/1 000 ml	60 g/l, 9 g/l	solution for infusion	intravenous use
Romania	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl starch Sodium chloride	HAES-steril 100 g/1 000 ml	100 g/l, 9 g/l	solution for infusion	intravenous use
Romania	B. BRAUN MELSUNGEN AG, Carl-Braun-Strasse 1 34212 Melsungen, Germany	Hydroxyethyl starch Sodium chloride	Venofundin 6 g/100 ml	60 g/l, 9 g/l	solution for infusion	intravenous use
Romania	S.C. Fresenius Kabi Romania S.R.L, strada Fanarului nr. 2A, 500464 Brasov, Romania	Hydroxyethyl starch, Sodium acetate trihydrate, Potassium chloride, Magnesium chloride hexahydrate, Sodium chloride	Volulyte 6 %	60 g/l, 4,63 g/l, 6,02 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use
Romania	B. BRAUN MELSUNGEN AG Carl-Braun. Str.1, D-34212 Melsungen, Germany	Hidroxietil amidon, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate, Calcium chloride dihydrate,Sodium acetate trihydrate, Malic acid	TETRASPAN 60 mg/ml	60 g/l, 6,252 g/l, 0,298 g/l, 0,203 g/l, 0,367 g/l, 3,266 g/l, 0,671 g/l	solution for infusion	intravenous use
Romania	B. BRAUN MELSUNGEN AG Carl-Braun. Str.1, D-34212 Melsungen, Germany	Hidroxietil amidon, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate, Calcium chloride dihydrate,Sodium acetate trihydrate, Malic acid	TETRASPAN 100 mg/ml	100 g/l, 6,252 g/l, 0,298 g/l, 0,203 g/l, 0,367 g/l, 3,266 g/l, 0,671 g/l	solution for infusion	intravenous use
Slovak Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	hydroxyethyl starch, Sodium chloride	HAES-steril 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	hydroxyethyl starch, Sodium chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Slovak Republic	BAXTER CZECH spol. s r.o. Karla Engliše 3201/6 150 00 Praha 5 Czech Republic	hydroxyethyl starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate	PlasmaVolume Redibag	60 g/l, 6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,70 g/l	solution for infusion	intravenous use
Slovak Republic	B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany	hydroxyethyl starch, Sodium chloride, Potassium chloride, Calcium chloride, Magnesium chloride hexahydrate, sodium acetate, Malic acid	Tetraspan 10 %	100 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g /l, 0,67 g/l	solution for infusion	intravenous use
Slovak Republic	B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany	hydroxyethyl starch, Sodium chloride, Potassium chloride, Calcium chloride, Magnesium chloride hexahydrate, sodium acetate, Malic acid	Tetraspan 6 %	60 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Slovak Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	hydroxyethyl starch, Sodium acetate trihydrate, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate	Volulyte 6 %, infúzny roztok	60 g/l, 4,63 g/l, 6,02 g/l, 0,30 g/l, 0,30 g/l	solution for infusion	intravenous use
Slovak Republic	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	hydroxyethyl starch, Sodium chloride	VOLUVEN	60 g/l, 9 g/l	solution for infusion	intravenous use
Slovak Republic	Fresenius Kabi s.r.o. Zeletavská 1525/1 140 00 Praha 4 - Michle Czech Republic	hydroxyethyl starch, Sodium chloride	Voluven 10 %	100 g/l, 9 g/l	solution for infusion	intravenous use
Slovenia	Medias International d.o.o. Leskoškova cesta 9D 1000 Ljubljana Slovenia	Hydroxyethyl Starch, Sodium chloride	HAES-steril 60 mg/ml raztopina za infundiranje	60,0 g/l, 9,0 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Slovenia	Baxter d.o.o. Zelezna cesta 18 1000 Ljubljana Slovenija	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate	Plasma Volume Redibag 60 mg/ml raztopina za infundiranje	60,0 g/l, 6,0 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l,	solution for infusion	intravenous use
Slovenia	B.Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan 60 mg/ml raztopina za infundiranje	60,0 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Slovenia	B.Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Sodium acetate trihydrate, Malic acid	Tetraspan 100 mg/ml raztopina za infundiranje	100,0 g/l, 6,25 g/l, 0,30 g/l, 0,37 g/l, 0,20 g/l, 3,27 g/l, 0,67 g/l	solution for infusion	intravenous use
Slovenia	Medias International d.o.o. Leskoškova cesta 9D 1000 Ljubljana Slovenia	Hydroxyethyl Starch, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate, Sodium acetate trihydrate	Volulyte 60 mg/ml raztopina za infundiranje	60,0 g/l, 6,02 g/l, 0,30 g/l, 0,30 g/l, 4,63 g/l	solution for infusion	intravenous use
Slovenia	Fresenius Kabi Deutschland GmbH 61346 Bad Homburg v.d.H Germany	Hydroxyethyl Starch, Sodium chloride	VOLUVEN 100 mg/ml raztopina za infundiranje	100,0 g/l, 9,0 g/l	solution for infusion	intravenous use
Slovenia	Medias International d.o.o. Leskoškova cesta 9D 1000 Ljubljana Slovenia	Hydroxyethyl Starch, Sodium chloride	VOLUVEN 60 mg/ml raztopina za infundiranje	60,0 g/l, 9,0 g/l	solution for infusion	intravenous use
Spain	B. BRAUN MELSUNGEN AG Carl-Braun Strasse, 1 Melsungen D-34212 Germany	Hydroxyethyl Starch + Sodium Chloride	HEMOES 6 % SOLUCIÓN	60 g/l + 9 g/l	solution for infusion	intravenous use
Spain	B. BRAUN MELSUNGEN AG Carl-Braun Strasse, 1 Melsungen D-34212 Germany	Hydroxyethyl Starch + Sodium Chloride	HEMOES 10 % SOLUCIÓN	100 g/l + 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl Starch + Sodium Chloride	VOLUVEN 6 % SOLUCIÓN PARA PERFUSIÓN	60 g/l + 9 g/l	solution for infusion	intravenous use
Spain	FRESENIUS KABI ESPAÑA S.A. Marina, 16-18-17 08005 Barcelona Spain	Hydroxyethyl Starch + Sodium Chloride	VOLUVEN 10 % SOLUCIÓN PARA PERFUSIÓN	100 g/l + 9 g/l	solution for infusion	intravenous use
Spain	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl Starch + Sodium Chloride	HES HIPERTONICO FRESENIUS SOLUCIÓN PARA PERFUSIÓN	60 g/l + 72 g/l	solution for infusion	intravenous use
Spain	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg v.d.H. Germany	Hydroxyethyl Starch + Sodium Acetate Trihydrate + Sodium Chloride + Potasium Chloride + Magnesium Chloride Hexahydrate	VOLULYTE 6 % SOLUCIÓN PARA PERFUSIÓN	60 g/l + 4,63 g/l + 6,02 g/l + 0,30 g/l + 0,30 g/l	solution for infusion	intravenous use
Spain	B. BRAUN MELSUNGEN AG Carl-Braun Strasse, 1 Melsungen D-34212 Germany	Hydroxyethyl Starch + Sodium Chloride + Potasium Chloride + Calcium Chloride Dihydrate + Magnesium Chloride Hexahydrate + Sodium Acetate Trihydrate + Malic Acid	ISOHES 6 % SOLUCIÓN PARA PERFUSIÓN	60 g/l + 6,25 g/l + 0,30 g/l + 0,37 g/l + 0,20 g/l + 3,27 g/l + 0,67 g/l	solution for infusion	intravenous use
Spain	B. BRAUN MELSUNGEN AG Carl-Braun Strasse, 1 Melsungen D-34212 Germany	Hydroxyethyl Starch + Sodium Chloride + Potasium Chloride + Calcium Chloride Dihydrate + Magnesium Chloride Hexahydrate + Sodium Acetate Trihydrate + Malic Acid	ISOHES 10 % SOLUCIÓN PARA PERFUSIÓN	100 g/l + 6,25 g/l + 0,30 g/l + 0,37 g/l + 0,20 g/l + 3,27 g/l + 0,67 g/l	solution for infusion	intravenous use
Spain	BAXTER S.L. Polígono Industrial Sector 14 Pouet de Camilo, 2 46394 Ribarroja del Turia (Valencia) Spain	Hydroxyethyl Starch + Sodium Chloride + Potasium Chloride + Calcium Chloride Dihydrate + Magnesium Chloride Hexahydrate + Sodium Acetate Trihydrate	PLASMAVOLUME REDIBAG SOLUCIÓN PARA PERFUSIÓN	60 g/l + 6 g/l + 0,4 g/l + 0,134 g/l + 0,2 g/l + 3,70 g/l	solution for infusion	intravenous use
Sweden	Fresenius Kabi AB, 751 74 Uppsala Sweden	Hydroxyethyl starch, 130/0.4, Sodium chloride	Voluven	60 g/l, 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Sweden	Fresenius Kabi AB, 751 74 Uppsala Sweden	Hydroxyethyl starch, 200/0.5, Sodium chloride	HyperHAES	60 g/l, 72 g/l	solution for infusion	intravenous use
Sweden	B. Braun Melsungen AG P.O. Box 1110 +1120 DE-34209 Melsungen Germany	Hydroxyethyl starch, 130/0.4, Sodium chloride	Venofundin®	60 g/l, 9 g/l	solution for infusion	intravenous use
Sweden	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	hydroxyethyl starch, 130/0.4, sodium chloride, sodium acetate trihydrate, malic acid, calcium chloride dihydrate, potassium chloride, magnesium chloride hexahydrate	Tetraspan	60 g/l, 6,252 g/l, 3,266 g/l, 0,671 g/l, 0,368 g/l, 0,298 g/l, 0,203 g/l	solution for infusion	intravenous use
Sweden	B. Braun Melsungen AG Carl-Braun-Strasse 1 34212 Melsungen Germany	hydroxyethyl starch, 130/0.4, sodium chloride, sodium acetate trihydrate, malic acid, calcium chloride dihydrate, potassium chloride, magnesium chloride hexahydrate	Tetraspan	100 g/l, 6,252 g/l, 3,266 g/l, 0,671 g/l, 0,368 g/l, 0,298 g/l, 0,203 g/l	solution for infusion	intravenous use
Sweden	Fresenius Kabi AB, 751 74 Uppsala Sweden	hydroxyethyl starch, 130/0.4, sodium chloride, sodium acetate trihydrate, magnesium chloride hexahydrate, potassium chloride	Volulyte	60 g/l, 6,020 g/l, 4,630 g/l, 0,300 g/l, 0,300 g/l	solution for infusion	intravenous use
Sweden	Baxter Medical AB Box 63 164 94 Kista Sweden	hydroxyethyl starch, 130/0.4, sodium chloride, sodium acetate trihydrate, potassium chloride, magnesium chloride hexahydrate, calcium chloride dihydrate	Hesra	60 g/l, 6,000 g/l, 3,700 g/l, 0,400 g/l, 0,200 g/l, 0,134 g/l	solution for infusion	intravenous use
Sweden	Fresenius Kabi AB, 751 74 Uppsala Sweden	Hydroxyethyl starch, 130/0.4, Sodium chloride	Voluven	100 g/l, 9 g/l	solution for infusion	intravenous use
The Netherlands	Fresenius Kabi Nederland B.V. Molenberglei 7 2627 Schelle Belgium	active substance: hydroxyethyl starch (MR 200.000), Sodium chloride	EloHAES, infusievloeistof	60,0 g/l, 9,0 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Fresenius Kabi Nederland B.V. Molenberglei 7 2627 Schelle Belgium	active substance: hydroxyethyl starch (MR 200.000)	HyperHAES, oplossing voor intraveneuze infusie 60 g/l	60,0 g/l	solution for infusion	intravenous use
The Netherlands	B. Braun Melsungen AG (Melsungen) Carl-Braun-Strasse 1 34212 Melsungen Germany	active substance: hydroxyethyl starch (MR 130.000) Sodium Chloride, malic acid, Calcium Chloride, Potassium Chloride, Magnesium Chloride, Sodium acetate	Tetraspan 10 % g/v, oplossing voor infusie 100 g/l	100,0 g/l, 9 g/l, 0,67 g/l, 0,37 g/l, 0,3 g/l, 0,2 g/l, 3,27 g/l	solution for infusion	intravenous use
The Netherlands	B. Braun Melsungen AG (Melsungen) Carl-Braun-Strasse 1 34212 Melsungen Germany	active substance: hydroxyethyl starch (MR 130.000) Sodium Chloride, malic acid, Calcium Chloride, Potassium Chloride, Magnesium Chloride, Sodium acetate	Tetraspan 6 % g/v, oplossing voor infusie 60 g/l	60,0 g/l, 6,25 g/l, 0,67 g/l, 0,37 g/l, 0,3 g/l, 0,2 g/l, 3,27 g/l	solution for infusion	intravenous use
The Netherlands	B. Braun Melsungen AG (Melsungen) Carl-Braun-Strasse 1 34212 Melsungen Germany	active substance: hydroxyethyl starch (MR 130.000), sodium chloride	Venofundin 60 mg/ml, oplossing voor intraveneuze infusie	60,0 g/l, 9 g/l	solution for infusion	intravenous use
The Netherlands	Fresenius Kabi Nederland B.V. Molenberglei 7 2627 Schelle Belgium	active substance: hydroxyethyl starch (MR 130.000), Sodium Chloride, Potassium Chloride, Magnesium Chloride, Sodium acetate, hydrochloric acid	Volulyte 6 % oplossing voor infusie	60,0 g/l, 6,02 g/l, 0,3 g/l, 0,3 g/l, 4,63 g/l, 0,3 g/l	solution for infusion	intravenous use
The Netherlands	Fresenius Kabi Nederland B.V. Molenberglei 7 2627 Schelle Belgium	active substance: hydroxyethyl starch (MR 130.000), sodium chloride	Voluven, 6 % (60 mg/ml) oplossing voor infusie	60,0 g/l, 0,9 g/l	solution for infusion	intravenous use
The Netherlands	Fresenius Kabi Nederland B.V. Molenberglei 7 2627 Schelle Belgium	active substance: hydroxyethyl starch (polymere 130/0.4) and sodium chloride	Voluven 10 % (100 mg/ml)	100 g/l, 9 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
The Netherlands	Baxter B.V. Kobaltweg 49 3542 CE UTRECHT/The Netherlands	Sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate, hydroxyethyl starch 130/0.42	Plasma Volume Redibag 6 %, solution for infusion	6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l, 60 g/l	solution for infusion	intravenous use
United Kingdom	Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE United Kingdom	Sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate, hydroxyethyl starch 130/0.42	Plasma Volume Redibag 6 % Solution for Infusion	6 g/l, 0,4 g/l, 0,134 g/l, 0,2 g/l, 3,7 g/l, 60 g/l	solution for infusion	intravenous use
United Kingdom	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn, Cheshire WA7 1NT United Kingdom	Hydroxyethyl starch 130/0.4, sodium chloride	Voluven 6 % solution for injection	60 g/l, 9 g/l	solution for infusion	intravenous use
United Kingdom	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn, Cheshire WA7 1NT United Kingdom	Hydroxyethyl starch 200/0.5, sodium chloride	Hyperhaes Solution for Injection	72 g/l, 60 g/l	solution for infusion	intravenous use
United Kingdom	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn, Cheshire WA7 1NT United Kingdom	Sodium acetate trihydrate, sodium chloride, potassium chloride, magnesium chloride hexahydrate, hydroxyethyl starch 130/0.4	Volulyte 6 % solution for infusion	4,63 g/l, 6,02 g/l. 0,3 g/l, 0,3 g/l, 60 g/l	solution for infusion	intravenous use
United Kingdom	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn, Cheshire WA7 1NT United Kingdom	Sodium chloride, hydroxyethyl starch 130/0.4	Voluven 6 % solution for infusion	9 g/l, 60 g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn, Cheshire WA7 1NT United Kingdom	Sodium chloride, hydroxyethyl starch 130/0.4	Voluven 10 % solution for infusion	9 g/l, 100 g/l	solution for infusion	intravenous use
United Kingdom	B Braun Melsungen AG Carl-Braun-Strasse 1 Melsungen, D-34212 Germany	Poly (O-2-hydroxyethyl) starch mol. sub. 0,45-0,55 AV. MW 200K, sodium chloride	Venofundin 6 % solution for infusion	60 g/l, 9 g/l	solution for infusion	intravenous use
United Kingdom	B Braun Melsungen AG Carl-Braun-Strasse 1 Melsungen, D-34212 Germany	Sodium chloride, potassium chloride, magnesium chloride hexahydrate, sodium acetate trihydrate, malic acid, poly (0-2-hydroxyethyl) starch, calcium chloride dihydrate	Tetraspan 6 % solution for infusion	6,25 g/l, 0,3 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l, 60 g/l, 0/37 g/l	solution for infusion	intravenous use
United Kingdom	B Braun Melsungen AG Carl-Braun-Strasse 1 Melsungen, D-34212 Germany	Sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate,sodium acetate trihydrate, malic acid, poly (0-2-hydroxyethyl) starch	Tetraspan 10 % solution for infusion	6,25 g/l, 0,3 g/l, 0,37 g/l, 0,2 g/l, 3,27 g/l, 0,67 g/l, 100 g/l	solution for infusion	intravenous use

ANNEX III

LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S), ROUTE(S) OF ADMINISTRATION, MARKETING AUTHORISATION HOLDER(S) IN THE MEMBER STATES

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	Hexal Pharma GmbH Stella-Klein-Löw-Weg 17 1020 Wien Austria	Metogastron 10 mg - Ampullen	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Austria	Hexal Pharma GmbH Stella-Klein-Löw-Weg 17 1020 Wien Austria	Metogastron 4 mg/ml - Tropfen	4 mg/ml	Oral drops, solution	Oral use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin - Filmtabletten	10 mg	Film-coated tablet	Oral use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin 10 mg - Ampullen	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin 50 mg - Konzentrat zur Infusionsbereitung	50 mg/10 ml	Concentrate for solution for infusion	Intravenous use
Austria	Abbott Products GmbH Perfektastraße 84A 1230 Wien Austria	Paspertin 4 mg/ml - Tropfen	4 mg/ml	Oral drops, solution	Oral use
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan	1 mg/ml	Oral solution	Oral use
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Belgium	Sanofi-Aventis Belgium N.V. Culliganlaan 1 C 1831 Diegem Belgium	Primperan 20 mg	20 mg	Suppository	Rectal use
Belgium	Takeda Belgium Gentsesteenweg 615 1080 Brussel Belgium	Dibertil	5 mg	Capsule, soft	Oral use
Belgium	Takeda Belgium Gentsesteenweg 615 1080 Brussel Belgium	Dibertil	10 mg	Capsule, soft	Oral use
Bulgaria	Sopharma PLC 16 Iliensko Shosse Str. Sofia 1220 Bulgaria	Antiemetin	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Bulgaria	Sopharma PLC 16 Iliensko Shosse Str. Sofia 1220 Bulgaria	Antiemetin	5 mg/ml	Syrup	Oral use
Bulgaria	AWD.pharma GmbH&Co.KG Wasastrasse 50 Radebeul 01445 Germany	Cerucal	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Bulgaria	Lek Pharmaceuticals d.d. Verovskova 57 Ljubljana 1526 Slovenia	Degan	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Bulgaria	Lek Pharmaceuticals d.d. Verovskova 57 Ljubljana 1526 Slovenia	Degan	10 mg	Tablet	Oral use
Bulgaria	CSC Pharmaceuticals Ltd. 10 Assen Yordanov str. Sofia 1592 Bulgaria	Pramidin 10	10 mg/spray	Nasal spray, solution	Nasal use
Bulgaria	CSC Pharmaceuticals Ltd. 10 Assen Yordanov str. Sofia 1592 Bulgaria	Pramidin 20	20 mg/spray	Nasal spray, solution	Nasal use
Bulgaria	Alkaloid Ltd 2 Ricardo Vakarini str. Sofia 1404 Bulgaria	Reglan	10 mg	Tablet	Oral use
Cyprus	Sanofi Aventis Cyprus ltd Charalambou Mouskou 14 2015 Strovolos Nicosia Cyprus	Primperan for adults suppository 20 mg	20 mg	Suppository	Rectal use
Cyprus	Sanofi Aventis Cyprus ltd Charalambou Mouskou 14 2015 Strovolos Nicosia Cyprus	Primperan solution for injection 10 mg/2 ml	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Cyprus	Sanofi Aventis Cyprus ltd Charalambou Mouskou 14 2015 Strovolos Nicosia Cyprus	Primperan tablets 10 mg	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	Medochemie ltd 1-10 Constantinoupoleos street P.O.BOX 51409 3505 Lemesos Cyprus	Elitan tablets 10 mg	10 mg	Tablet	Oral use
Cyprus	Medochemie ltd 1-10 Constantinoupoleos street P.O.BOX 51409 3505 Lemesos Cyprus	Elitan injection 10 mg/2 ml	10 mg/2 ml	Injection	Intramuscular use Intravenous use
Cyprus	Remedica ltd Aharnon street P.O.Box 51706 3508 Lemesos Cyprus	Cloperan tablets 10 mg	10 mg	Tablet	Oral use
Cyprus	Accord Healthcare Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramide Accord 10 mg tablet	10 mg	Tablet	Oral use
Czech Republic	Lek Pharmaceuticals d.d. Verovškova 57 1526 Ljubljana Slovenia	Degan 10 mg tablety	10 mg	Tablet	Oral use
Czech Republic	Lek Pharmaceuticals d.d. Verovškova 57 1526 Ljubljana Slovenia	Degan 10 mg roztok pro injekci	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Czech Republic	Hexal AG Industriestrasse 25 83607 Holzkirchen Germany	Mcp hexal 10	10 mg	Tablet	Oral use
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague Czech Republic	Cerucal	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Teva Pharmaceuticals CR, s.r.o. Radlická 3185/1c 150 00 Prague Czech Republic	Cerucal	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Denmark	Sanofi-aventis Denmark A/S Slotsmarken 13 DK-2970 Hørsholm Denmark	Primperan	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Denmark	Sanofi-aventis Denmark A/S Slotsmarken 13 DK-2970 Hørsholm Denmark	Primperan	20 mg	Suppository	Rectal use
Denmark	Orion Corporation Orionintie 1A FI-02200 Espoo Finland	Emperal	10 mg	Tablet	Oral use
Denmark	Temmler Pharma GmbH & Co KG, Temmlerstrasse 2 DE-35039 Marburg Germany	Gasto-Timelets	30 mg	Prolonged-release capsule, hard	Oral use
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	CERUCAL	10 mg	Tablet	Oral use
Finland	sanofi-aventis Oy Huopalahdentie 24 00350 Helsinki Finland	Primperan	20 mg	Suppository	Rectal use
Finland	sanofi-aventis Oy Huopalahdentie 24 00350 Helsinki Finland	Primperan	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Finland	sanofi-aventis Oy Huopalahdentie 24 00350 Helsinki Finland	Primperan	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 10 mg, comprimé sécable	10 mg	Tablet	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 10 mg, suppositoire sécable	10 mg	Suppository	Rectal use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 20 mg, suppositoire	20 mg	Suppository	Rectal use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN ENFANTS 2,6 mg/ml, solution buvable	2,6 mg/ml	Oral solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN NOURRISSONS ET ENFANTS 2,6 mg/ml, solution buvable	2,6 mg/ml	Oral drops, solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 0,1 % ADULTES, solution buvable édulcorée au cyclamate de sodium et à la saccharine sodique	0,10 %	Oral drops, solution	Oral use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 0,1 %, solution buvable édulcorée à la saccharine sodique	0,10 %	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 10 mg/2 ml, solution injectable en ampoule	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
France	Sanofi Aventis France 1-13, boulevard Romain Rolland 75014 Paris France	PRIMPERAN 100 mg, solution injectable	100 mg/5 ml	Solution for injection	Intramuscular use Intravenous use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	CHLORHYDRATE DE METOCLOPRAMIDE RENAUDIN 10 mg/2 ml, solution injectable en ampoule	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	CHLORHYDRATE DE METOCLOPRAMIDE RENAUDIN 20 mg/ml, solution injectable	20 mg/ml	Solution for injection	Intramuscular use Intravenous use
France	Panpharma ZI du Clairay Luitré 35133 Fougères France	DICHLORHYDRATE DE METOCLOPRAMIDE PANPHARMA 100 mg/5 ml, solution injectable (IM, IV) en ampoule	100 mg/100 ml	Solution for injection	Intramuscular use Intravenous use
France	Laboratoires Richard rue du Progrès ZI des Reys de Saulce 26270 Saulce sur Rhone France	CHLORHYDRATE DE METOCLOPRAMIDE RICHARD 1 mg/ml, solution buvable	1 mg/ml	Oral solution	Oral use
France	Mylan SAS 117, allée des Parcs 69800 Saint-Priest France	METOCLOPRAMIDE MYLAN 10 mg, comprimé sécable	10 mg	Tablet	Oral use
France	Sandoz 49, avenue Georges Pompidou 92300 Levallois-Perret France	METOCLOPRAMIDE SANDOZ 10 mg, comprimé sécable	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	Meda Pharma France 25, boulevard de l'Amiral Bruix 75016 Paris France	ANAUSIN METOCLOPRAMIDE 15 mg, comprimé à libération prolongée	15 mg	Prolonged-release tablet	Oral use
France	Techni-Pharma 7, rue de l'Industrie BP 717 98014 Monaco Cedex Monaco	PROKINYL L.P. 15 mg, gélule à libération prolongée	15 mg	Prolonged-release capsule, hard	Oral use
Germany	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching Germany	MCP Tropfen-1 A-Pharma	4,21 mg/1 g	Oral solution	Oral use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin 10 mg/2 ml Ampullen	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin 50 mg/10 ml Ampullen	50 mg/10 ml	Concentrate for solution for infusion	Intravenous use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin Filmtabletten	10 mg	Film-coated tablet	Oral use
Germany	Abbott Arzneimittel GmbH Freundallee 9A 30173 Hannover Germany	Paspertin Tropfen	4 mg/ml	Oral solution	Oral use
Germany	AbZ-Pharma GmbH Graf-Arco-Str. 3 89079 Ulm Germany	MCP AbZ 5 mg/ml Tropfen	5,91 mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	MCP AL 10	10,53 mg	Tablet	Oral use
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	MCP AL retard	30 mg	Prolonged-release capsule, hard	Oral use
Germany	ALIUD PHARMA GmbH Gottlieb-Daimler-Str. 19 D-89150 Laichingen Germany	MCP AL Tropfen	4,21 mg/1 ml	Oral solution	Oral use
Germany	AWD.pharma GmbH & Co.KG Wasastr. 50 D-01445 Radebeul Germany	Cerucal inject	10,54 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Germany	AWD.pharma GmbH & Co.KG Wasastr. 50 D-01445 Radebeul Germany	Metoclopramid AWD 10 mg Tabletten	10,53 mg	Tablet	Oral use
Germany	axcount Generika AG Max-Planck-Str. 36b D-61381 Friedrichsdorf Germany	MCP axcount Tropfen	4,21 mg/ml	Oral solution	Oral use
Germany	betapharm Arzneimittel GmbH Kobelweg 95 D-86156 Augsburg Germany	MCP-beta Tropfen	4,21 mg/ml	Oral solution	Oral use
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 79079 Ulm Germany	MCP-CT 10 mg/2 ml Ampullen	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 79079 Ulm Germany	MCP-CT 30 mg Retardkapseln	30 mg	Prolonged-release capsule, hard	Oral use
Germany	CT Arzneimittel GmbH Graf-Arco-Str. 3 79079 Ulm Germany	MCP-CT 4 mg/1 ml Tropfen	5,2 mg/ml	Oral solution	Oral use
Germany	DOCPHARM Arzneimittelvertrieb GmbH & Co Greschbachstr. 7 D-76229 Karlsruhe Germany	Metoclopramid Injektionslösung 10 ml PB	52,65 mg/10 ml	Solution for injection	Intravenous use
Germany	Dolorgiet GmbH & Co.KG Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	465 mg/100 ml	Oral solution	Oral use
Germany	Dolorgiet GmbH & Co.KG Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	8,92 mg	Tablet	Oral use
Germany	hameln pharmaceuticals GmbH Langes Feld 13 D-31789 Hameln Germany	Metoclo-hameln 5 mg/ml, Injektionslösung	10,53 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil 10 mg Amp.	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil 20 mg Supp.	20 mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil 50 mg Amp.	52,7 mg/10 ml	Solution for injection	Intravenous use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil akut Tropfen	5,97 mg/ml	Oral solution	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil retard	31,6 mg	Prolonged-release capsule, hard	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil retard mite	15,8 mg	Prolonged-release capsule, hard	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrosil Tabletten	10,54 mg	Tablet	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	Gastrsosil Tropfen	5,97 mg/ml	Oral solution	Oral use
Germany	Heumann Pharma GmbH & Co. Generica KG Südwestpark 50 D-90449 Nürnberg Germany	MCP Heumann 10 mg Tabletten	10,53 mg	Tablet	Oral use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal 10	10,53 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal injekt	10,53 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Germany	HEXAL AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal Tropfen	4,21 mg/ml	Oral solution	Oral use
Germany	Mylan dura GmbH Wittichstr. 6 D-64295 Darmstadt Germany	MCP dura 4 mg/ml Tropfen zum Einnehmen	4,21 mg/ml	Oral solution	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm 10 mg Tabletten	11,82 mg	Tablet	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm 10 mg Zäpfchen	10 mg	Suppository	Rectal use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-Ratiopharm 30 mg Retardkapseln	30 mg	Prolonged-release capsule	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm 4 mg/ml Tropfen	5,2 mg/ml	Oral solution	Oral use
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm SF 10 mg/2 ml Injektionslösung	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Germany	ratiopharm GmbH Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP-ratiopharm SF 50 mg/10 ml Konzentrat zur Herstellung einer Infusionslösung	50 mg/10 ml	Concentrate for solution for infusion	Intravenous use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 D-83607 Holzkirchen Germany	MCP Sandoz 10 mg Tabletten	10,53 mg	Tablet	Oral use
Germany	Sandoz Pharmaceuticals GmbH Raiffeisenstr. 11 D-83607 Holzkirchen Germany	MCP Sandoz 4 mg/ml Tropfen zum Einnehmen, Lösung	4,21 mg/ml	Oral solution	Oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel Germany	MCP STADA 10 mg Tabletten	10,53 mg	Tablet	Oral use
Germany	Stadapharm GmbH Stadastr. 2 - 18 D-61118 Bad Vilbel Germany	MCP STADA 4 mg/1 ml Tropfen zum Einnehmen, Lösung	4,21 mg/ml	Oral solution	Oral use
Germany	Temmler Pharma GmbH & Co.KG Temmlerstr. 2 D-35039 Marburg Germany	Cerucal	10,54 mg	Tablet	Oral use
Germany	Temmler Pharma GmbH & Co.KG Temmlerstr. 2 D-35039 Marburg Germany	Cerucal retard	30 mg	Prolonged-release capsule, hard	Oral use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	10 mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	20 mg	Suppository	Rectal use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	5 mg/5 ml	Syrup	Oral use
Greece	Sanofi Aventis AEBE 348 Syngrou avenue Building A 176 74 Kalithea – Athens Greece	PRIMPERAN	10 mg	Tablet	Oral use
Hungary	AWD Pharma GmbH&Co. KG Wasastrasse 50 Radebeul 1445 Germany	CERUCAL 5 mg/ml oldatos injekció	5 mg/ml	Solution for injection	Parenteral use
Hungary	AWD Pharma GmbH&Co. KG Wasastrasse 50 Radebeul 1445 Germany	CERUCAL tabletta	10 mg	Tablet	Oral use
Iceland	Nycomed Pharma AS P.O Box 205 NO-1375, Asker Norway	Afipran	10 mg	Tablet	Oral use
Iceland	Nycomed Pharma AS P.O Box 205 NO-1375, Asker Norway	Afipran	20 mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Iceland	Nycomed Pharma AS P.O Box 205 NO-1375, Asker Norway	Afipran	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Ireland	Mercury Pharmacuticals (Ireland) Ltd 4045 Kingswood Road Citywest Business Park Co. Dublin Ireland	Metoclopramide	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Ireland	Amdipharm Limited Regency House Miles Gray Road Basildon Essex, SS14 3AF United Kingdom	Maxolon	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Ireland	Amdipharm Limited Regency House Miles Gray Road Basildon Essex, SS14 3AF United Kingdom	Maxolon	10 mg	Tablet	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	1 mg/ml	Syrup	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	4 mg/ml	Oral drops, solution	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	PLASIL	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	Teofarma srl Via Fratelli Cervi, 8 27010 Valle Salimbene Pavia Italy	RANDUM	10 mg	Tablet	Oral use
Italy	F.I.R.M.A. spa Via Scandicci, 37 50143 Firenze Italy	CLOPAN	10 mg	Solution for injection	Intramuscular use Intravenous use
Italy	Sirton Medicare spa Piazza XX Settembre, 2 22079 Villa Guardia - COMO Italy	PRAMIDIN	10 mg/spray	Nasal spray, solution	Nasal use
Italy	Sirton Medicare spa Piazza XX Settembre, 2 22079 Villa Guardia - COMO Italy	PRAMIDIN	20 mg/spray	Nasal spray, solution	Nasal use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	DIGESTIVO S.PELLEGRINO	5 mg	Effervescent tablet	Oral use
Italy	Sanofi-Aventis spa Viale Luigi BODIO, 37/B 20158 Milano Italy	DIGESTIVO S.PELLEGRINO	5 mg	Effervescent granules	Oral use
Italy	Hospira Italia srl Via Orazio, 20/22 80122 NAPOLI Italy	METOCLOPRAMIDE CLORIDRATO HOSPIRA	10 mg	Solution for injection	Intramuscular use Intravenous use
Italy	Farmakopea spa Via Cavriana, 14 20134 MILANO Italy	ISAPRANDIL	5 mg	Effervescent tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	Farmakopea spa Via Cavriana, 14 20134 MILANO Italy	ISAPRANDIL	5 mg	Effervescent granules	Oral use
Latvia	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma 10 mg tablets	10 mg	Tablet	Oral use
Latvia	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma 10 mg/2 ml solution for injection	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Latvia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cerucal 10 mg tablets	10 mg	Tablet	Oral use
Lithuania	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Cerucal	10 mg	Tablet	Oral use
Lithuania	Medochemie Ltd. p.o box 51409 CY-3505, Limassol Cyprus	ELITAN	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Lithuania	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma	10 mg	Tablet	Oral use
Lithuania	Pharmaceutical Works POLPHARMA SA 19 Pelplińska Street 83-200 Starogard Gdański Poland	Metoclopramid Polpharma	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Nycomed Belgium s.a. 615, chaussee de Gand B-1080 Bruxelles Belgium	Dibertil	10 mg	Capsule, soft	Oral use
Luxembourg	Nycomed Belgium s.a. 615, chaussee de Gand B-1080 Bruxelles Belgium	Dibertil	5 mg	Capsule, soft	Oral use
Luxembourg	Dolorgiet Gmbh&Co Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	4,65 mg/ml	Oral drops	Oral use
Luxembourg	Dolorgiet Gmbh&Co Otto-von-Guericke-Str. 1 D-53757 Sankt Augustin Germany	Gastronerton	8,92 mg	Tablet	Oral use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm	5,2 mg	Oral drops	Oral use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm	10 mg	Suppository	Rectal use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm	10 mg	Tablet	Oral use
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	mcP Ratiopharm SF	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Luxembourg	Ratiopharm GMBH Arzneimittel Graf-Arco-Str. 3 D-89079 Ulm Germany	MCP Ratiopharm-30	30 mg	Modified-release capsule, soft	Oral use
Luxembourg	Eurogenerics s.a. Heizel Esplanade B22 1020 Laeken Belgium	Metoclopramide EG-10	10 mg	Capsule, soft	Oral use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan adultes	20 mg	Suppository	Rectal use
Luxembourg	Hexal AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal-10	10 mg	Tablet	Oral use
Luxembourg	Hexal AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal Injekt	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Luxembourg	Hexal AG Industriestr. 25 D-83607 Holzkirchen Germany	MCP Hexal Tropfen	4 mg/ml	Oral drops	Oral use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10 mg	Tablet	Oral use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Luxembourg	Sanofi-Aventis Belgium Culliganlaan 1 C 1831 Diegem Belgium	Primperan	1 mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Malta	Accord Healthcare Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramide 10 mg tablets	10 mg	Tablet	Oral use
Malta	Antigen International Limited Chandler House Castle Street, Roscrea County Tipperary Ireland	Metoclopramide Injection BP 10 mg/2 ml Solution for Injection	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Malta	Hameln Pharmaceuticals Ltd. Nexus, Gloucester Business Park Gloucester GL3 4AG United Kingdom	Metoclopramide 5 mg/ml Injection	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Malta	Medochemie Limited 1-10 Constantinoupleos Str 3011 Limassol Cyprus	Elitan 10 mg tablet	10 mg	Tablet	Oral use
Malta	Medochemie Ltd. 1-10, Constantinoupleos Street 3011 Limassol Cyprus	Elitan Injection, 10 mg/2 ml, Solution for Injection	10 mg	Solution for injection	Intramuscular use Intravenous use
Malta	Remedica Ltd. Limassol Industrial Estate Aharnon Street P.O. Box 51706 3508 Limassol Cyprus	Cloperan 10	10 mg	Tablet	Oral use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan injectie 10/2 ml, oplossing voor injection 10 mg/2 ml	10 mg/2 ml	Solution for injection	Intravenous use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan drank, drank 1 mg/ml	1 mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan 10, zetpillen 10 mg	10 mg	Suppository	Rectal use
Netherlands	Sanofi-Aventis Netherlands B.V. Kampenringweg 45 D-E 2803 PE GOUDA The Netherlands	Primperan 20, zetpillen 20 mg	20 mg	Suppository	Rectal use
Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA HAARLEM The Netherlands	Metoclopramide HCl 10 PCH, tabletten 10 mg	10 mg	Tablet	Oral use
Netherlands	Centrafarm B.V. Nieuwe Donk 3 4879 AC Etten Leur The Netherlands	Metoclopramide HCl CF 10 mg, tabletten	10 mg	Tablet	Oral use
Netherlands	Accord Healthcare B.V. De Waterman 15 A 4891 TL Rijsbergen The Netherlands	Metoclopramidemonohydrochloride Accord 10 mg Tabletten	10 mg	Tablet	Oral use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	20 mg	Suppository	Rectal use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	100 mg/ml	Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	1 mg/ml	Oral solution	Oral use
Norway	Nycomed Pharma AS Postboks 205 1372 Asker Norway	Afipran	10 mg	Tablet	Oral use
Poland	Zakłady Farmaceutyczne Polpharma SA ul. Pelplińska 19 83-200 Starogard Gdański Poland	Metoclopramidum 0,5 % Polpharma	5 mg/ml	Solution for injection	Intramuscular use Intravenous use
Poland	Zakłady Farmaceutyczne Polpharma SA ul. Pelplińska 19 83-200 Starogard Gdański Poland	Metoclopramidum Polpharma	10 mg	Tablet	Oral use
Portugal	Sanofi - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal	Primperan	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros Portugal	Metoclopramida Labesfal	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Portugal	Labesfal - Laboratórios Almiro, S.A. Zona Industrial do Lagedo 3465-157 Santiago de Besteiros Portugal	Metoclopramida Labesfal	10 mg	Tablet	Oral use
Portugal	Sanofi - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal	Primperan	1 mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Sanofi - Produtos Farmacêuticos, Lda. Empreendimento Lagoas Park Edifício 7 - 3º Piso 2740-244 Porto Salvo Portugal	Primperan	10 mg	Tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. l Ribeiro de Pavia, 1 - 1º - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro de Pavia 1 - 1 - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	10 mg	Tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro de Pavia 1 - 1 - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	2,6 mg/ml	Oral drops, solution	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A. Rua Manuel Ribeiro de Pavia 1 - 1 - Venda Nova 2700-547 Amadora Portugal	Metoclopramida Medinfar	1 mg/ml	Oral solution	Oral use
Romania	S.C. LAROPHARM S.R.L. Șos. Alexandriei, nr 145 A B07-Bragadiru, jud Ilfov România	METOCLOPRAMID LAROPHARM	10 mg	Tablet	Oral use
Romania	S.C. SLAVIA PHARM S.R.L. B-dul Theodor Pallady nr. 44C Sector 3, București 032266 România	METOCLOPRAMID	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	S.C. MEDUMAN S.A. Str. Aleea Eroilor nr. 28, Vișeu de Sus, Județul Maramureș 435700 România	N - METOCLOPRAMID	10 mg	Tablet	Oral use
Romania	S.C. ARENA GROUP S.A Str. Stefan Mihaileanu, nr.31 sector 2; Bucuresti 024022 România	METOCLOPRAMID ARENA 10 mg	10 mg	Tablet	Oral use
Romania	S.C. TERAPIA S.A. Str. Fabricii nr. 124 Cluj - Napoca 400632 România	METOCLOPRAMID 10 mg	10 mg	Tablet	Oral use
Romania	S.C. BIOFARM S.A. Str. Logofăt Tăutu, nr. 99 sector 3, București 031212 Romania	METOCLOPRAMID BIOFARM 1 mg/5 ml	1 mg/5 ml	Syrup	Oral use
Romania	S.C. BIOFARM S.A. Str. Logofăt Tăutu, nr. 99 sector 3, București 031212 Romania	METOCLOPRAMID	7 mg/ml	Oral drops, solution	Oral use
Romania	S.C. TERAPIA S.A. Str. Fabricii nr. 124 Cluj - Napoca 400632 România	METOCLOPRAMID 10 mg	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Romania	Accord Healthcar Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramid Accord 10 mg comprimate	10 mg	Tablet	Oral use
Slovak Republic	TEVA Pharmaceuticals Slovakia s.r.o. Teslova 26 82102 Bratislava Slovakia	Cerucal	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Slovak Republic	AWD. pharma GmbH & Co.KG Wasastr. 50 01445 Radebeul Germany	Cerucal	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Slovak Republic	Sandoz Pharmaceuticals d.d. Verovškova 57 1000 Ljubljana Slovenia	DEGAN 10 mg	10 mg	Tablet	Oral use
Slovak Republic	Sandoz Pharmaceuticals d.d. Verovškova 57 1000 Ljubljana Slovenia	DEGAN 10 mg/2 ml	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Slovenia	Alkaloid-INT d.o.o. Ljubljana Slandrova ulica 4 1231 Ljubljana- Crnuce Slovenia	Reglan 1 mg/1 ml peroralna raztopina	1 mg/ml	Oral solution	Oral use
Slovenia	Alkaloid-INT d.o.o. Ljubljana Slandrova ulica 4 1231 Ljubljana- Crnuce Slovenia	Reglan 10 mg tablete	10 mg	Tablet	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 10 mg/2 ml SOLUCION INYECTABLE	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 1 mg/1 ml SOLUCION ORAL	1 mg/ml	Oral solution	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 10 mg COMPRIMIDOS	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 260 mg/100 ml GOTAS	2,6 mg/ml	Oral drops, solution	Oral use
Spain	Sanofi Aventis, S.A. Josep Plá, 2 08019 Barcelona Spain	PRIMPERAN 100 mg/5 ml SOLUCION INYECTABLE	100 mg/5 ml	Solution for injection	Intramuscular use Intravenous use
Spain	Kern Pharma, S.L. Venus, 72. Poligono Industrial Colon II. 08228 Tarrasa Spain	METOCLOPRAMIDA KERN PHARMA 1 mg/ml SOLUCION ORAL	1 mg/ml	Oral solution	Oral use
Spain	Pensa Pharma, S.A.U Jorge Comín (médico pediatra) 3 - 46015 Valencia Spain	METOCLOPRAMIDA PENSA 1 mg/ml SOLUCION ORAL	1 mg/ml	Oral solution	Oral use
Spain	Accord Healthcare, S.L.U. Moll de Barcelona s/n World Trade Centre Edifici Est 6ª planta 08039 Barcelona Spain	METOCLOPRAMIDA ACCORD 10 mg COMPRIMIDOS	10 mg	Tablet	Oral use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Primperan	10 mg	Tablet	Oral use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Primperan	10 mg/2 ml	Solution for injection	Intramuscular use Intravenous use
Sweden	sanofi-aventis AB Box 14142 167 14 Bromma Sweden	Primperan	20 mg	Suppository	Rectal use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Actavis UK Limited Whiddon Valley Barnstaple North evon EX32 8NS United Kingdom	Metoclopramide Tablets BP 10 mg	10 mg	Tablet	Oral use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon SR	15 mg	Modified-release capsules, hard	Oral use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon Tablets 10 mg	10 mg	Tablet	Oral use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon Injection 5 mg/ml	0,5 % w/v	Solution for injection	Intramuscular use Intravenous use
United Kingdom	Amdipharm plc Regency House Miles Gray Road, Basildon Essex SS14 3AF United Kingdom	Maxolon High Dose 100 mg/20 ml	0,5 % w/v	Solution for injection	Intravenous use
United Kingdom	Chelonia Healthcare Limited Boumpoulinas 11, 3rd Floor Nicosia, CY-1060 Cyprus	Metoclopramide 10 mg Tablets	10 mg	Tablet	Oral use
United Kingdom	Crescent Pharma Limited Units 3 & 4 Quidhampton Business Units Polhampton Lane, Overton Hampshire RG25 3ED United Kingdom	Metoclopramide 10 mg Tablets	10 mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Ennogen Limited 78 York Street London W1H 1DP United Kingdom	Metoclopramide 10 mg Tablets	10 mg	Tablet	Oral use
United Kingdom	Ennogen Limited 78 York Street London W1H 1DP United Kingdom	Metoclopramide 5 mg/ml Injection	0,5 % w/v	Solution for injection	Intramuscular use Intravenous use
United Kingdom	Generics (United Kingdom) Limited Station Close, Potters Bar Hertfordshire EN6 1TL United Kingdom	Metoclopramide Tablets 10 mg	10 mg	Tablet	Oral use
United Kingdom	Hameln Pharmaceuticals Limited Nexus, Gloucester Business Park Gloucester GL3 4AG United Kingdom	Metoclopramide Injection BP 5 mg/ml	0,526 % w/v	Solution for injection	Intramuscular use Intravenous use
United Kingdom	Metwest Pharmaceuticals Limited 15 Runnelfield Harrow on the Hill Middlesex HA1 3NY United Kingdom	Metoclopramide 10 mg Tablets	10 mg	Tablet	Oral use
United Kingdom	Pharmvit Limited 177 Bilton Road, Perivale Middlesex UB6 7HQ United Kingdom	Metoclopramide Tablets BP 10 mg	10 mg	Tablet	Oral use
United Kingdom	Rosemont Pharmaceuticals Limited Rosemont House Yorkdale Industrial Park Braithwaite Street Leeds, W Yorkshire LS11 9XE United Kingdom	Metoclopramide Hydrochloride 5 mg/5 ml Oral Solution	5 mg/5 ml	Oral solution	Oral use
United Kingdom	Rosemont Pharmaceuticals Limited Rosemont House Yorkdale Industrial Park Braithwaite Street Leeds, W Yorkshire LS11 9XE United Kingdom	Maxolon Paediatric Liquid	5 mg/5 ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Teva United Kingdom Limted Brampton Road Hampden Park, Eastbourne East Sussex BN22 9AG United Kingdom	Primperan; Metoclopramide Tablets BP 10 mg	10 mg	Tablet	Oral use
United Kingdom	Accord Healthcare Ltd Sage House 319 Pinner Road North Harrow Middlesex HA1 4HF United Kingdom	Metoclopramide Hydrochloride 10 mg tablets	10 mg	Tablet	Oral use
United Kingdom	Mercury Pharma International Limited 4045 Kingswood Raod City West Business Park County Dublin Ireland	Metoclopramide 5 mg/ml solution for injection	5 mg/ml	Solution for injection	Intramuscular use Intravenous use

ANNEX IV

LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S), ROUTE(S) OF ADMINISTRATION, MARKETING AUTHORISATION HOLDER(S) IN THE MEMBER STATES

Member State (in EEA)	Marketing Authorisaton Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin Fas 4,5 mg Filmtabletten	4,5 mg (1:1:1)	film-coated tablet	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 1 mg/ml Tropfen	1 mg/ml (1:1:1)	oral drops, solution	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 3 mg/ml Tropfen	3 mg/ml (1:1:1)	oral drops, solution	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 1 mg Tabletten	1 mg (1:1:1)	tablet	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin 2 mg Tabletten	2 mg (1:1:1)	tablet	oral use
Austria	Defiante Farmaceutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal/Madeira, Portugal	Hydergin SRO 6 mg Kapseln	6 mg (1:1:1)	modified-release capsule, hard	oral use
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine	1 mg-ml	oral solution	oral use
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine	1,5 mg	Tablets	oral use

Member State (in EEA)	Marketing Authorisaton Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine	4,5 mg	Tablets	oral use
Belgium	Defiante Farmacêutica S.A., Rua dos Ferreiros 260, 9000-082 Funchal, Portugal	Hydergine FAS	4,5 mg	Gastro-resistant tablet	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	1,5 mg	Tablets	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	1 mg-ml	oral solution	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	3 mg-ml	oral solution	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	Ibexone	4,5 mg	Tablets	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	STOFILAN	1,5 mg	Tablets	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	STOFILAN	1 mg-ml	oral drops solution	oral use
Belgium	Nycomed Belgium N.V. Gentsesteenweg 615 1080 Brussels Belgium	STOFILAN FORTE	4,5 mg	Tablets	oral use

Member State (in EEA)	Marketing Authorisaton Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Czech Republic	TEVA Czech Industries s.r.o. Ostravská 29 747 70 Opava-Komárov Czech Republic	SECATOXIN FORTE	2,5 MG/ML	Oral drops, solution	oral use
Finland	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1,5 mg	Tablets	oral use
Finland	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg	Tablets	oral use
France	THERICA 15, avenue Henry Dunant 27400 Louviers France	CAPERGYL 4,5 mg DOSE QUOTIDIENNE UNIQUE, capsule	4,5 mg	soft capsule	oral use
France	DEFIANTE FARMACEUTICA SA (PORTUGAL) Rua dos Ferreiros, 260 9000-082 Funchal Portugal	HYDERGINE 1 mg/ml, solution buvable en gouttes	1 mg/ml	oral drops, solution	oral use
France	DEFIANTE FARMACEUTICA SA (PORTUGAL) Rua dos Ferreiros, 260 9000-082 Funchal Portugal	HYDERGINE 4,5 mg DOSE QUOTIDIENNE UNIQUE, comprimé	4,5 mg	tablet	oral use
Germany	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	2 mg	Tablets	oral use
Germany	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg/ml	Oral drops	oral use
Germany	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	2 mg/ml	Oral drops	oral use

Member State (in EEA)	Marketing Authorisaton Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Greece	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergine	1 mg/ml	Oral drops	oral use
Italy	Defiante Farmaceutica sa Rua dos Ferreiros, 260 Funchal Madeira - Portugal	HYDERGINA	1,5 mg	tablet	oral use
Italy	Defiante Farmaceutica sa Rua dos Ferreiros, 260 Funchal Madeira - Portugal	HYDERGINA	1 mg/ml	oral solution	oral use
Luxembourg	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg/ml	Oral drops	oral use
Luxembourg	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	2 mg/ml	Oral drops	oral use
Poland	Farmaceutyczna Spółdzielnia Pracy FILOFARM ul. Pułaskiego 39 85-619 Bydgoszcz Poland	Dihydroergotoxinum Filofarm	1 mg/ml	oral solution	oral use
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	1,5 mg	tablet	oral use
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	4,5 mg	tablet	oral use
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	1 mg/ml	Oral drops, solution	oral use

Member State (in EEA)	Marketing Authorisaton Holder	(Invented) Name	Strength	Pharmaceutical form	Route of administration
Portugal	Defiante Farmacêutica, S.A. PRT Rua dos Ferreiros, 260 9000-082 Funchal - Madeira Portugal	Hydergine	3 mg/ml	Oral drops, solution	oral use
Romania	LEK PHARMACEUTICALS d.d. Verovskova 57, 1526 Ljubljana, Slovenia	REDERGIN	1 mg/ml	Oral drops, solution	oral use
Slovak Republic	Teva Czech Industries s.r.o. Ostravská 29, č. p. 305 747 70 Opava- Komárov Czech republic	SECATOXIN FORTE	2,5 mg / 1 ml	Oral drops, solution	oral use
Slovenia	LEK farmacevtska družba d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia	Redergin 1,5 mg tablete	1,5 mg	tablet	oral use
Slovenia	LEK farmacevtska družba d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia	Redergin 4,5 mg tablete	4,5 mg	tablet	oral use
Slovenia	LEK farmacevtska družba d.d., Verovskova 57, SI-1526 Ljubljana, Slovenia	Redergin 1 mg/ ml peroralna raztopina	1 mg/ml	oral solution	oral use
Spain	DEFIANTE FARMACEUTICA, S.A. Rua dos Ferreiros, 260 9000-082 Funchal PORTUGAL	HYDERGINA SOLUCIÓN GOTAS	1 mg/ml	oral drops, solution	oral use
Spain	DEFIANTE FARMACEUTICA, S.A. Rua dos Ferreiros, 260 9000-082 Funchal PORTUGAL	HYDERGINA 4,5 mg COMPRIMIDOS	4,5 mg	tablet	oral use
Sweden	Defiante Farmacêutica, S.A. Rua dos Ferreiros, 260 9000-082 Funchal Portugal	Hydergin	1 mg	Tablets	oral use