Annex I

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

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 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
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

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	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
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

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 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	60,0g/l, 6g/l, 0,400g/l, 0,134g/l, 0,2g/l, 3,70g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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%	60g/l, 6.02g/l, 4.63g/l, 0.3g/l, 0.3g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl starch + Sodium chloride	VOLUVEN SOLUTION FOR INFUSION 10%	100g/l, 9g/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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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 1000 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 1000 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 1000 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 1000 ml	solution for infusion	intravenous use
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 1000 ml	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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 1000 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 1000 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 1000 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 60MG/ML	60 g/l, 6.25 g/l, 0,3 g/l, 0.37g/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 100MG/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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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

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 pour perfusion en poche	6 g / 100 ml	solution for infusion	intravenous use
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

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 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
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

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, 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
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

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	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

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	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
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

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 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 %	100g/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	60g/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 200000) + Sodium Chloride	HAES-STERIL	60g/l+9g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Greece	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl Starch + Sodium Chloride	VOLUVEN	60g/l+9g/l	solution for infusion	intravenous use
Greece	FRESENIUS KABI HELLAS AE Mesogeion Avenue 354, Agia Paraskevi 15341, Athens Greece	Hydroxyethyl Starch + Sodium Chloride	VOLUVEN	100g/l+9g/l	solution for infusion	intravenous use
Greece	VIOSER SA, 9th Km National Highway Trikala-Larissis, P.O. Box 35, Taxiarhes, Trikala, Trikala 42100 Greece	Hydroxyethyl Starch + Sodium Chloride	VENOFUNDIN	60g/l+9g/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 200000) + sodium acetate trihydrate + sodium chloride + potassium chloride + magnesium chloride hexahydrate	VOLULYTE	60g/l, 4.63g/l, 6.02g/l, 0.3g/l, 0.3g/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	60g/l+6g/l+0,4g/l +0,134g/l+0,2g/l +3,7g/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 Trikal-Larissa, P.O. Box 35, Taksiarhes Trikalon, Trikala 42100 Greece	Poly(o-2-hydroxyethyl)starch (M.W 200000) + 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 200000) + 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

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	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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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, 0.2g/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	60g/l, 6.25g/l, 0.3g/l, 0.37g/l, 0.2g/l, 3.27g/l, 0.67g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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	100g/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
Ireland	Fresenius Kabi Limited Cestrian Court Eastgate way Manor Park Runcorn,Cheshire WA7 1NT United Kingdom	poly (0-2-hydroxyethyl)starch sodium chloride	HyperHAES	60g/l, 72g/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 9.00g/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 chloride	Voluven 6% Solution for Infusion (Glass bottle)	60g/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	60g/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)	60g/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 acetate trihydrate sodium chloride potassium chloride magnesium chloride hexahydrate	Volulyte 6% Solution for Infusion, polyoelfine bags	60g/l, 4.63g/l, 6.02g/l, 0.3g/l, 0.3g/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	60g/l, 4.63g/l, 6.02g/l, 0.3g/l, 0.3g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
Italy	FRESENIUS KABI ITALIA Srl Via Camagre, 41-43 Isola della Scala (Verona) 37063 Italy	Hydroxyethyl starch, Sodium Chloride	Vonten	100 g/l , 9g/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	60g/l, 72g/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	60g/l, 9g/l	solution for infusion	intravenous use
Italy	B. Braun Melsungen AG Carl-Braun-Straße 1 34209 Melsungen Germany	Hydroxyethyl starch, Sodium Chloride	Amidolite	60g/l, 9g/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	60g/l, 6,25g/l, 0,30g/l, 0,37g/l, 0,20g/l, 3,27g/l, 0,67g/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	100g/l, 6,25g/l, 0,30g/l, 0,37g/l, 0,20g/l, 3,27g/l, 0,67g/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	60g/l, 6g/l, 0,4g/l, 0,134g/l, 0,2g/l, 3,7g/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	60g/l, 6,02g/l, 0,3g/l, 0,3g/l, 4,63g/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	60g/l, 9g/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, 9g/l	solution for infusion	intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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 + 0,67g /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, 9g/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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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, 9g/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
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, 6g/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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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

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 10%	100 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	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

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	Potassium chloride + Sodium acetate trihydrate + Magnesium chloride hexahydrate + Hydroxyethyl starch + Sodium chloride	Volulyte	0.3 mg/ml + 4.63mg/ml + 0.3mg/ml + 60mg/ml + 6.02mg/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 + 3.27mg/ml + 0.67mg/ml + 0.2mg/ml + 6.25mg/ml + 60mg/ml + 0.37mg/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 + 3.27mg/ml + 0.67mg/ml + 0.2mg/ml + 6.25mg/ml + 100mg/ml + 0.37mg/ml	solution for infusion	intravenous use
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 + 0.4mg/ml + 0.2mg/ml + 60mg/ml + 0.134mg/ml + 6mg/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	Voluven Fresenius	100 mg/ml + 9mg/ml	solution for infusion	intravenous use
Romania	S.C. INFOMED FLUIDS S.R.L., B-dul Theodor Pallady nr. 50, sector 3, Bucureşti, 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/1000 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 Braşov, 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, Bucureşti, 032266 Romania	Hydroxyethyl starch Sodium chloride	INFOHES 60 g/L	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	S.C. INFOMED FLUIDS S.R.L. B-dul Theodor Pallady nr. 50, sector 3, Bucureşti, 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
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 60g/1000 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/1000 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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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 %	100g/l, 9g/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	60g/l, 72g/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	60g/l, 6g/l, 0.4g/l, 0.134g/l, 0.2g/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 %	100g/l, 6,25g/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 %	60g/l, 6,25g/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
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	60g/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	60g/l, 9g/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 %	100g/l, 9g/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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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
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

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 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

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, 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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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

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 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
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

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	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
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

Member State (in EEA)	Marketing authorisation holder	INN	Product name	Strength	Pharmaceutical form	Route of administration
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 II

Scientific conclusions and grounds for variation to the terms of the marketing authorisations and detailed explanation for the differences from the PRAC recommendation

Scientific conclusions and grounds for the variation to the terms of the marketing authorisations subject to conditions and detailed explanation for the differences from the PRAC recommendation

The CMDh considered the below PRAC recommendations following the procedure under Article 107i of Directive 2001/83/EC dated 10 October 2013 with regards to Hydroxyethyl starch containing medicinal products solutions for infusion:

1. Overall summary of the scientific evaluation of solutions for infusion containing hydroxyethyl starch medicinal products by PRAC

Hydroxyethyl starch (HES) solutions for infusion include products with starch derived from potato or corn with different molecular weights and substitution ratios. HES containing solutions for infusion were indicated mainly for the treatment and prophylaxis of hypovolaemia and hypovolemic shock.

HES solutions have been the object of two reviews. The first review was initially started under the framework of Article 31 of Directive 2001/83/EC. The PRAC issued a recommendation on available data for this review in June 2013, concluding that HES solutions should be suspended in all patient populations. Following requests for re-examination by marketing authorisation holders (MAHs), the PRAC confirmed its previous position under the Article 31 in October 2013. While the re-examination was ongoing some Member States decided to suspend or limit the marketing or use of these medicines in their territories. In accordance with the EU legislation, this type of action required that an EU review procedure be carried out. Consequently, a second review of HES solutions under Article 107i of Directive 2001/83/EC was initiated, and it ran separately but in parallel with the re-examination of the Article 31, also finalising in October 2013. However, it must be noted that new evidence was considered in the procedure under Article 107i of Directive 2001/83/EC. This new evidence was not available when the PRAC recommendation on the procedure under Article 31 of Directive 2001/83/EC was issued in June 2013 and could therefore not be considered in the re-examination of the latter in October 2013. It is on the basis of the totality of the data available, including the new evidence, that the PRAC issued conclusion on the procedure provided for in Article 107i of Directive 2001/83/EC in October 2013. Therefore the conclusions on the Article 107i of Directive 2001/83/EC reflect the most complete and up-to-date evaluation of the available data relating to the HES containing medicinal products.

Details of this recommendation are presented hereafter.

Under the framework of Article 107i of Directive 2001/83/EC, the PRAC considered recommendations on HES rendered in the referral under Article 31 of Directive 2001/83/EC and also reviewed available data including clinical studies, meta-analyses of clinical studies, post-marketing experience, responses submitted by the marketing authorisation holders (MAHs) in writing and at oral explanations, spontaneous reports on the safety and efficacy of hydroxyethyl starch containing products for solutions for infusion, as well as stakeholders' submissions in particular with regards to the risk of mortality and renal failure.

On the basis of the available data, in particular results from VISEP, 6S and CHEST studies, the PRAC concluded that HES is associated with an increased risk of mortality and renal failure in patients with sepsis, in critically ill and burn patients and that the benefits of HES do not outweigh the risks in these patient populations.

However, it was noted that short-term haemodynamic improvements have been observed in other patient populations, including surgical and trauma patients. Whilst recognising the limitations of these studies which included limited size and short duration of follow-up, the PRAC noted that some volume

sparing effect was reported in Madi-Jebara *et al.* 2008, that suggested that HES 130/0.4 6% seems to have benefits over twice the volume of Ringer's lactate in preventing spinal anaesthesia induced hypotension. Some benefit for elective surgical patients has also been shown in short-term surrogate hemodynamic outcomes along with a modest volume sparing effect (Hartog *et al*. 2011). In hypovolaemic patients with normal pulmonary function, the use of colloids to maintain colloid-osmotic pressure may limit the development of peripheral as well as pulmonary oedema (Vincent JL 2000). Some publications also suggest that colloids might help to prevent positive fluid balance and/or over-infusion of fluids (Wills 2005, Naing CM and Win DK 2010). Some of authors argue that a positive net fluid balance is associated with a decrease in organ perfusion and an increased mortality (e.g. Sadaka F *et al*. 2013, Payen D *et al*. 2008). Meybohm P *et al*. 2013 suggest that use of HES should be restricted to the initial phase of volume resuscitation with a maximum time interval of 24 h. Martin *et al* 2002 showed that HES treatment resulted in a significantly lower estimated blood loss and that there was no difference in red blood cells, or blood product utilisation among the groups. Hamaji et al 2013 also showed that significantly fewer red blood cell transfusions were required in the HES group.

Therefore, the PRAC noted the available data from studies in surgical and trauma patients and considered that although these studies were limited in size and duration of follow-up they did provide some reassurance that the risks of mortality and renal injury in surgical and trauma patients may be lower than those in the critically ill and sepsis patients. Although the mechanisms by which increased renal injury and mortality occur is not well established, it is possible that the degree of inflammatory processes seen in sepsis and critically ill patients is greater and associated with significant capillary leakage compared with other patient populations such as the perioperative setting after elective surgery or un-complicated trauma where the systematic inflammatory process and the extent of capillary leak may be lower.

New results from CRYSTAL have also become available. Despite the studies' limitations which were noted, the results from the CRYSTAL study comparing colloids to crystalloids showed that in patients with hypovolaemia, the use of colloids vs crystalloids did not result in a significant difference in 28-day mortality. Although 90-day mortality was lower among patients receiving colloids, this requires further investigations. In addition, in the BaSES study, the hospitalisation time was significantly reduced in patients treated with 6% HES 130/0.4 compared to 0.9% NaCl. Results from the RaFTinG registry in intensive care units, an observational, non-randomised study aiming to gather more information in 'real-life' clinical practice showed no statistically significant differences between patients treated with crystalloids only (n=2482) and those treated with colloids (all HES preparations and gelatin, n=2063) for the endpoints of 90-day mortality. The PRAC therefore acknowledged the results of this studies which shows no risk of mortality associated with the use of HES but considered that given the limitations of this study its findings could not negate the findings from 6S and VISEP studies that had shown an increased risk of mortality in critically ill patients.

Additional expert advice was sought from an ad-hoc expert group. The experts agreed that the benefits may be observed in severe hypovolaemia in short duration only at the beginning i.e. perioperative setting and disappearing faster with patient's stabilisation. The experts suggested that benefit of HES may be seen in particular in perioperative bleeding.

Therefore, the PRAC agreed that the therapeutic indication of hydroxyethyl starch containing products should be restricted to treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient. However additional measures must be implemented to minimise potential risks in these patients. HES solutions should be restricted to the initial phase of volume resuscitation with a maximum time interval of 24 h. The posology section should identify the maximum daily dose and should recommend that the lowest possible effective dose should be employed. HES products are contraindicated in patients with renal impairment or renal replacement therapy but the contraindications should also be extended to include other patient populations including patients with

sepsis, critically ill patients and burns patients. The PRAC considered that the use of HES must be discontinued at the first sign of renal injury. Monitoring of renal function in patients is recommended for at least 90 days. Particular caution should be exercised when treating patients with impaired hepatic function or in patients with blood coagulation disorders. The product information will be updated to reflect these restrictions and warnings.

In addition, two phase IV randomised clinical trials with an appropriate control and clinically meaningful endpoints will need to be conducted to provide more evidence on the efficacy and safety, including the risk of 90-day mortality and renal failure, in perioperative and trauma populations. An European drug utilisation study will also be conducted to evaluate the effectiveness of the recommended risk minimisation measures. Protocols and results of these studies will be submitted to national competent authorities according to agreed timelines. The MAHs are also encouraged to submit risk management plans to national competent authorities.

Benefit risk balance

In view of the totality of the evidence available in the procedure under Article 107i of Directive 2001/83/EC, the PRAC considered that Hydroxyethyl starch should be restricted to the treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient subject to agreed restrictions, contraindications, warnings, other changes to the product information and additional risk minimisation measures.

The PRAC conclusion in the context of the referral procedure under Article 107i of Directive 2001/83/EC included additional data that was not available when the PRAC issued its recommendation on the referral in accordance with Article 31 of Directive 2001/83/EC in June 2013 and therefore could not be considered in the re-examination of the latter in October 2013. Therefore the conclusions on the Article 107i of Directive 2001/83/EC reflect the most complete and up-to-date evaluation of the available data relating to the HES containing medicinal products.

Grounds for PRAC recommendation

Whereas,

- The Pharmacovigilance Risk Assessment Committee (PRAC) considered the procedure under Article 107i of Directive 2001/83/EC, for hydroxyethyl starch containing products for solutions for infusion.
- The PRAC noted the conclusions of a review under article 31 of Directive 2001/83/EC. However, for the current procedure under Article 107i of Directive 2001/83/EC the PRAC reviewed new available data, with a focus on risk of mortality and renal failure, including clinical studies, meta-analyses of clinical studies, post-marketing experience, responses submitted by the marketing authorisation holders (MAHs) in writing and at oral explanations and stakeholders' submissions.
- The PRAC considered that the use of hydroxyethyl starch is associated with an increased risk of mortality and renal replacement therapy or renal impairment in patients with sepsis, critically ill and burn patients.
- The PRAC considered, in view of the new evidence which includes data from clinical trials, further expert advice, new proposals for additional risk minimisation measures, including restrictions on use and a commitment from the MAHs to perform additional studies in patients with trauma and in elective surgery, that the benefit of hydroxyethyl starch containing products outweighs the risk in the treatment of hypovolaemia due to acute blood loss when

crystalloids alone are not considered sufficient. This is subject to restrictions, warnings and other changes to the product information.

- The PRAC concluded that hydroxyethyl starch containing products should be contraindicated in patients with sepsis, in critically ill and burn patients. In addition, special warnings in surgery and trauma patients have been included.
- The PRAC also concluded that there was need for further risk minimisation measures such as information to patients and healthcare professionals. Core elements of a direct healthcare professional communication were agreed, together with the timelines for distribution, and that studies should be conducted. The PRAC also considered that studies should be conducted to provide more evidence on the efficacy and safety of hydroxyethyl starch in the perioperative setting and trauma.

The PRAC concluded that the benefit-risk balance for hydroxyethyl starch containing medicinal products remains favourable in treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient subject to the agreed restrictions, contraindications, warnings, other changes to the product information and additional risk minimisation measures.

The PRAC conclusion in the context of the referral procedure under Article 107i of Directive 2001/83/EC included additional data that was not available when the PRAC issued its recommendation on the referral in accordance with Article 31 of Directive 2001/83/EC in June 2013 and therefore could not be considered in the re-examination of the latter in October 2013. Therefore the conclusions on the Article 107i reflect the most complete and up-to-date evaluation of the available data relating to HES containing medicinal products.

2. Detailed explanation for the differences from the PRAC recommendation

Having reviewed the PRAC recommendation, the CMDh agreed with the overall scientific conclusions and grounds for recommendation. However, with regards to the two phase IV randomised clinical trials (RCTs) requested to provide more evidence on the efficacy and safety in perioperative and trauma populations, including the risk of 90-day mortality and renal failure, , the CMDh encouraged the MAHs to jointly submit common study protocols. To this end the MAHs were strongly advised to seek scientific advice with the European Medicines Agency, in time for the submission of the study protocols to the national competent authorities (NCAs) within 6 months of the European Commission Decision. Consequently the CMDh decided that synopsis were not required in advance of the recommended scientific advice.

The CMDh amended the due date for the submission of the protocol of the drug utilisation study which is now also due within 6 months of the European Commission Decision in order to harmonise submission dates of all conditions.

In view of the above and considering that the study protocols of the drug utilisation study and of the two randomised clinical trials are conditions to the marketing authorisation, the CMDh noted that these elements should be reflected in a risk management plan. Companies had been encouraged to submit core elements of the risk management plan, but the CMDh considered that this should be a condition. The MAHs should submit within 6 months of the European Commission Decision, the core elements (including protocol of DUS, protocols of the RCTs) of a risk management plan in EU format and this was included in Annex IV.

The CMDh also considered that the direct healthcare professional communication (DHPC) should be submitted to the NCAs where HES products are marketed, within one week of the CMDh adopted position as per agreed communication plan.

CMDh position

The CMDh having considered the PRAC recommendation dated 10 October 2013 pursuant to Article 107k(1) and (2) of Directive 2001/83/EC and the oral explanations by the Marketing Authorisation Holders on 21 October 2013, reached a position on the variation to the terms of the marketing authorisations of Hydroxyethyl starch solutions for infusion containing medicinal products for which the relevant sections of the summary of product characteristics and package leaflet are set out in Annex III and subject to the conditions set out in Annex IV.

Annex III

Amendments to relevant sections of the summary of product characteristics and package leaflet

Note:

The relevant sections of the Summary of Product Characteristics and package leaflet are the outcome of the referral procedure.

The product information shall be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

I. Summary of Product Characteristics

<▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.>

[...]

Section 4.1 Therapeutic indications

[The wording of this section should be read as below]

Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient. (see sections 4.2, 4.3 and 4.4)

Section 4.2 Posology and method of administration

[This section should be amended to reflect the following wording]

Use of HES should be restricted to the initial phase of volume resuscitation with a maximum time interval of 24 h.

The first 10-20 ml should be infused slowly and under careful monitoring of the patient so that any anaphylactoid reaction can be detected as early as possible.

The maximum daily dose is *<30ml/kg for 6% HES (130/0.40) and 6% HES (130/0.42); for other HES products the maximum daily dose should be recalculated accordingly>*.

The lowest possible effective dose should be applied. Treatment should be guided by continuous haemodynamic monitoring so that the infusion is stopped as soon as appropriate haemodynamic goals have been achieved. The maximum recommended daily dose must not be exceeded.

Paediatric population:
Data are limited in children therefore it is recommended not to use HES products in this population.

[...]

Section 4.3 Contraindications

[This section should be amended to include the following contraindications]

- hypersensitivity to the active substances or to any of the other excipients listed in section 6.1
- sepsis
- burns
- renal impairment or renal replacement therapy
- intracranial or cerebral haemorrhage
- critically ill patients (typically admitted to the intensive care unit)
- hyperhydration
- pulmonary oedema
- dehydration
- hyperkalaemia *[only applicable to products containing potassium]*
- severe hypernatraemia or severe hyperchloraemia
- severely impaired hepatic function
- congestive heart failure
- severe coagulopathy
- organ transplant patients

[...]

Section 4.4 Special warnings and precautions for use

[This section should be amended to reflect the following wording]

Because of the risk of allergic (anaphylactoid) reactions, the patient should be monitored closely and the infusion instituted at a low rate (see section 4.8).

Surgery and trauma:
There is a lack of robust long term safety data in patients undergoing surgical procedures and in patients with trauma. The expected benefit of treatment should be carefully weighed against uncertainty with regard to this long term safety. Other available treatment options should be considered.

The indication for volume replacement with HES has to be considered carefully, and haemodynamic monitoring is required for volume and dose control. (See also section 4.2.)

Volume overload due to overdose or too rapid infusion must always be avoided. The dosage must be adjusted carefully, particularly in patients with pulmonary and cardiocirculatory problems. Serum electrolytes, fluid balance and renal function should be monitored closely.

HES products are contraindicated in patients with renal impairment or renal replacement therapy (see section 4.3). The use of HES must be discontinued at the first sign of renal injury.
An increased need for renal replacement therapy has been reported up to 90 days after HES administration. Monitoring of renal function in patients is recommended for at least 90 days.

Particular caution should be exercised when treating patients with impaired hepatic function or in patients with blood coagulation disorders.
Severe haemodilution resulting from high doses of HES solutions must also be avoided in the treatment of hypovolaemic patients.
In the case of repeated administration, blood coagulation parameters should be monitored carefully.
Discontinue the use of HES at the first sign of coagulopathy.
In patients undergoing open heart surgery in association with cardiopulmonary bypass the use of HES products is not recommended due to the risk of excess bleeding.

Paediatric population:
Data are limited in children therefore it is recommended not to use HES products in this population. (see section 4.2)

[...]

Section 4.8 Undesirable effects

[This following wording should be reflected in this section]

[...]

Hepatic injury < frequency not known (cannot be estimated from the available data)>
Renal injury < frequency not known (cannot be estimated from the available data)>

[...]

II. Package Leaflet

< ▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects. >

[…]

1. What <*Product name*> is and what it is used for

[This section should be amended to include the below wording]

<*Product name*> is a plasma volume substitute that is used to restore the blood volume when you have lost blood when other products called crystalloids are not considered sufficient alone.

[…]

2. What you need to know before you use <*Product name*>

Do not use <*Product name*> if you:

[This section should be amended to include the below wording]

- are allergic to any of the active substances or any of the other ingredients of this medicine
- suffer from serious generalised infection (sepsis)
- suffer from burn injury
- have kidney impairment or receive dialysis
- have severe liver disease
- suffer from bleeding in the brain (intracranial *or cerebral* bleeding)
- are critically ill (e.g. you need to stay in an intensive care unit)
- have too much fluid in your body and you have been told that you have a condition known as hyperhydration
- have fluid in the lungs (pulmonary oedema)
- are dehydrated
- have been told that you have a severe increase of potassium [Note: only for products which contain potassium], sodium or chloride in your blood
- have severely impaired liver function
- have severe heart failure
- have severe problems with your blood clotting
- have received an organ transplant

[…]

Warnings and precautions

[This section should be amended to include the below wording]

It is important to tell your doctor if you have:
- impairment of your liver function
- problems with your heart or circulation
- blood clotting (coagulation) disorders
- problems with your kidneys

Because of the *risk of allergic* (anaphylactic/anaphylactoid*) reactions*, you will be monitored closely to detect early signs of an allergic reaction when you receive this medicine.

Surgery and trauma:
Your doctor will consider carefully if this medicine is suitable for you.

Your doctor will adjust the dose of <*Product name*> carefully in order to prevent fluid overload. This will be done especially if you have problems with your lungs or with your heart or circulation.

The nursing staff will also take measures to observe your body's fluid balance, blood salt level, and kidney function. If necessary you may receive additional salts.

In addition it will be ensured that you receive enough fluids.

<Product name> is contraindicated if you have kidney impairment or of kidney injury requiring dialysis.
If impaired kidney function occurs during therapy:
If the doctor detects first signs of kidney impairment he/she will stop giving you this medicine. In addition your doctor may need to monitor your kidney function for up to 90 days.

If you are given *<Product name>* repeatedly your doctor will monitor the ability of your blood to clot, bleeding time and other functions. In case of an impairment of the ability of your blood to clot, your doctor will stop giving you this medicine.

If you are undergoing open heart surgery and you are on a heart-lung machine to assist in pumping your blood during the surgery, the administration of this solution is not recommended.

[...]

3. How to use <Product name>

[This section should be amended to include the below wording]

Dosage
Your doctor will decide on the correct dose for you to receive.
Your doctor will use the lowest possible effective dose and will not infuse *<Product name>* for more than 24 hours.
The maximum daily dose is *<30ml/kg for 6% HES (130/0.40) and 6% HES (130/0.42); for other HES products the maximum daily dose should be recalculated accordingly>*.

Use in children
There is only limited experience of the use of this medicine in children. Therefore it is not recommended to use this medicine in children.

[...]

4. Possible side effects

[This section should be amended to include the below wording]

[...]

Frequency not known (cannot be estimated from the available data)
- Kidney injury
- Liver injury

Reporting of side effects
If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

[...]

Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisations

National competent authorities of Member State(s) or reference Member State(s) if applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

Conditions	Date
The MAH(s) should perform two phase IV randomised clinical trials (RCTs) with an appropriate control and clinically meaningful endpoints to demonstrate the efficacy and safety in the perioperative setting and trauma. The primary composite endpoint is 90-day mortality and 90-days renal failure. The secondary endpoints are: - major peri-operative complications (e.g. infections, bleedings, anastomosis insufficiency, reoperation rate, diagnosis of pulmonary oedema). - Haemodynamic stabilisation in relation to dose (e.g. Heart rate, mean arterial pressure, central venous pressure, central venous oxygen saturation, serum lactate level, base excess and urine output) - length of stay, morbidity, coagulation, inflammation, hospital mortality - measurement of creatinine (GFR) 1/ The protocol of the studies should be submitted to the NCAs 2/ Final study reports by:	1/ Within 6 months after EC decision 2/ End of 2016
The MAH(s) should conduct a drug utilisation study in several Member States to evaluate the effectiveness of the risk minimisation measures taken. Study protocol by: Final study report by:	Within 6 months after EC decision Within 24 months after protocol agreement
The MAH(s) should submit the core elements (including protocol of DUS, protocol of the RCTs) of a risk management plan in EU format.	Within 6 months after EC decision
DHPC Communication circulation according to the PRAC agreed communication plan and conditions.	Within 1 week from CMDh adopted position