



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2022
EMA/605749/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydroxyethyl starch

Procedure no.: EMEA/H/N/PSR/J/0031

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Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Austria	Fresenius Kabi Austria GmbH	Volulyte 6% infusionslösung	Magnesium chloride hexahydrate, potassium chloride, sodium chloride, sodium acetate trihydrate, hydroxyethyl starch 130/0.4	Solution For Infusion	Intravenous Use
Austria	Fresenius Kabi Austria GmbH	Voluven (HES 130/0,4) 6% infusionslösung	Sodium chloride, hetastarch	Solution For Infusion	Intravenous Use
Belgium	Fresenius Kabi nv/sa	Volulyte 6% infusionslösung/6% oplossing voor Infusie/ 6% solution pour perfusion	Magnesium chloride hexahydrate, potassium chloride, sodium chloride, sodium acetate trihydrate, hydroxyethyl starch 130/0.4	Solution For Infusion	Intravenous Use
Belgium	Fresenius Kabi nv/sa	Voluven, 6% (60 mg/ml) Infusionslösung, Voluven, 6% (60 mg/ml) oplossing voor infusie, Voluven, 6% (60 mg/ml) solution pour perfusion	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4	Solution For Infusion	Intravenous Use
Belgium	Fresenius Kabi nv/sa	Voluven, 10% (100 mg/ml) Infusionslösung, Voluven, 10% (100 mg/ml) oplossing voor infusie, Voluven, 10% (100 mg/ml) solution	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
		pour perfusion			
Belgium	B. Braun Melsungen AG	Tetraspan 6% oplossing voor infusie	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Hetastarch 60g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml, L-Malic Acid 0.67g/1000ml	Solution For Infusion	Intravenous Use
Bulgaria	Fresenius Kabi Bulgaria EOOD	Волулайт 6% инфузионен разтвор	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Bulgaria	Fresenius Kabi Deutschland GmbH	ВОЛУВЕН 6% инфузионен разтвор	Sodium chloride, hetastarch	Solution For Infusion	Intravenous Use
Croatia	Fresenius Kabi d.o.o.	Volulyte 6% otopina za infuziju	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
			4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml		
Croatia	Fresenius Kabi d.o.o.	Voluven 6% otopina za infuziju	Sodium chloride, hetastarch	Solution For Infusion	Intravenous Use
Cyprus	Fresenius Kabi Deutschland GmbH	Volulyte 6%, Διάλυμα για έγχυση	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Czechia	Fresenius Kabi Deutschland GmbH	Volulyte 6% infuzní roztok	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Czechia	Fresenius Kabi s.r.o.	VOLUVEN 6% INFUZNÍ ROZTOK	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Czechia	Fresenius Kabi s.r.o.	Voluven 10%, infuzní roztok	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Denmark	Fresenius Kabi AB	Volulyte, infusionsvæske, opløsning	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Denmark	Fresenius Kabi AB	Voluven	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Denmark	Fresenius Kabi AB	Voluven	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Estonia	Fresenius Kabi Deutschland GmbH	Volulyte	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Estonia	Fresenius Kabi Polska Sp. z o.o.	Voluforte	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Estonia	Fresenius Kabi Deutschland GmbH	Voluven	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Finland	Fresenius Kabi AB	Volulyte 60 mg/ml infuusioneste, liuos	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Poly (O-2-Hydroxyethyl) Starch 130/0.4 (Ph.Eur.) 60g/1000ml	Solution For Infusion	Intravenous Use
Finland	Fresenius Kabi AB	Voluven 100 mg/ml infuusioneste, liuos	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Finland	Fresenius Kabi AB	Voluven 60 mg/ml infuusioneste, liuos	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
France	Fresenius Kabi France S.A.S.	Volulyte 6%, solution pour perfusion	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
France	Fresenius Kabi France S.A.S.	Voluven, solution pour perfusion	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
France	B. Braun Melsungen AG	ISOVOL 6%, solution pour perfusion	Magnesium Chloride Hexahydrate 0.203g/1000ml, Potassium Chloride 0.298g/1000ml, Sodium Chloride 6.252g/1000ml, Calcium Chloride Dihydrate 0.367g/1000ml, Malic Acid 0.671g/1000ml, Sodium Acetate Trihydrate 3.266g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
France	B. Braun Melsungen AG	Restorvol perfusion 6% solution pour	Sodium Chloride 9g/1000ml, Hetastarch 60g/1000ml	Solution For Infusion	Intravenous Use
Germany	Fresenius Kabi Deutschland GmbH	Volulyte 6% Infusionslösung	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Poly (O-2-Hydroxyethyl) Starch 130/0.4 (Ph.Eur.) 60g/1000ml	Solution For Infusion	Intravenous Use
Germany	Fresenius Kabi Deutschland GmbH	Volulyte 6% Infusionslösung	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl,	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
			Hydroxyethyl Starch 130/0.4 60gl		
Germany	Fresenius Kabi Deutschland GmbH	Voluven 10 % Infusionslösung	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Germany	Fresenius Kabi Deutschland GmbH	Voluven 6 %; Infusionslösung	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Germany	Fresenius Kabi Deutschland GmbH	Voluven 6 % Infusionslösung	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Germany	Fresenius Kabi Deutschland GmbH	Voluven Fresenius; 6 % Infusionslösung	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Germany	B. Braun Melsungen AG	Tetraspan 6% Infusionslösung	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Hetastarch 60g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml, L-Malic Acid 0.67g/1000ml	Solution For Infusion	Intravenous Use
Germany	B. Braun Melsungen AG	Tetraspan 10% Infusionslösung	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Hetastarch 100g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml, L-Malic Acid 0.67g/1000ml	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Germany	B. Braun Melsungen AG	Venofundin 60 mg/ml Infusionslösung	Sodium Chloride 9g/1000ml, Hetastarch 60g/1000ml	Solution For Infusion	Intravenous Use
Greece	Fresenius Kabi Hellas A.E.	Volulyte 6%W/V, Διάλυμα για έγχυση	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Greece	Fresenius Kabi Hellas A.E.	Voluven 6% διάλυμα για έγχυση	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Hungary	Fresenius Kabi Deutschland GmbH	Volulyte 6% oldatos infúzió	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Poly (O-2-Hydroxyethyl) Starch 130/0.4 (Ph.Eur.) 60g/1000ml	Solution For Infusion	Intravenous Use
Hungary	Fresenius Kabi Deutschland GmbH	Volulyte 6% oldatos infúzió	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Poly (O-2-Hydroxyethyl) Starch 130/0.4 (Ph.Eur.) 60g/1000ml	Solution For Infusion	Intravenous Use
Hungary	Fresenius Kabi Deutschland GmbH	Voluven 10 % oldatos infúzió	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Hungary	Fresenius Kabi Deutschland GmbH	Voluven 6 % oldatos infúzió	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Iceland	Fresenius Kabi AB	Volulyte 60 mg/ml innrennslislyf, lausn	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Iceland	Fresenius Kabi AB	Volulyte 60 mg/ml innrennslislyf, lausn	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Iceland	Fresenius Kabi AB	Voluven 6%. Innrennslislyf, lausn.	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Italy	Fresenius Kabi Italia S.r.l.	Volulyte 6% Soluzione per infusione	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Italy	Fresenius Kabi Italia S.r.l.	Volulyte 6% Soluzione per infusione	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Italy	Fresenius Kabi Italia S.r.l.	Voluven soluzione per infusione al 6%	Sodium Chloride 9g/1000ml, Poly (O-2-Hydroxyethyl) Starch 130/0.4 (Ph.Eur.) 60g/1000ml	Solution For Infusion	Intravenous Use
Italy	Fresenius Kabi Italia S.r.l.	Voluven soluzione per infusione al 6%	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Latvia	Fresenius Kabi Deutschland GmbH	Volulyte 6% šķīdums infūzijām	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Latvia	Fresenius Kabi Deutschland GmbH	Volulyte 6% šķīdums infūzijām	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Latvia	Fresenius Kabi Deutschland GmbH	Voluven 6% šķīdums infūzijām	Sodium Chloride 9g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Lithuania	Fresenius Kabi Deutschland GmbH	Volulyte 6% infuzinis tirpalas	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Lithuania	Fresenius Kabi Polska Sp. z o.o.	Voluforte 10% infuzinis tirpalas	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Lithuania	Fresenius Kabi Deutschland GmbH	Voluven 6 % infuzinis tirpalas	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Luxembourg	Fresenius Kabi Deutschland GmbH	Volulyte 6% Infusionslösung	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Luxembourg	Fresenius Kabi Deutschland GmbH	Voluven 6 % Infusionslösung	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Malta	Fresenius Kabi Italia S.r.l.	Volulyte 6% Solution for Infusion	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Netherlands	Fresenius Kabi Nederland b.v.	Volulyte 6% oplossing voor infusie	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Netherlands	Fresenius Kabi Nederland b.v.	Voluven, 10% (100 mg/ml) oplossing voor infusie	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 100gl	Solution For Infusion	Intravenous Use
Netherlands	Fresenius Kabi Nederland b.v.	Voluven, 6% (60 mg/ml) oplossing voor infusie	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Norway	Fresenius Kabi Norge AS	Volulyte 60 mg/ml infusjonsvæske, oppløsning	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Norway	Fresenius Kabi Norge AS P	Voluven 60 mg/ml infusjonsvæske, oppløsning	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Poland	Fresenius Kabi Deutschland GmbH	Volulyte 6%, roztwór do infuzji	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Poland	Fresenius Kabi Polska Sp. z o.o.	Voluven 10%, 10% + 0,9%, roztwór do infuzji	Sodium Chloride 9g, Hydroxyethyl Starch 130/0.4 100g	Solution For Infusion	Intravenous Use
Poland	Fresenius Kabi Deutschland GmbH	VOLUVEN, (60 mg + 9 mg)/ml, roztwór do infuzji	Sodium Chloride 9g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Poland	B. Braun Melsungen AG	Tetraspan 60 mg/ml HES roztwór do infuzji	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml, Poly (O 2 Hydroxyethyl) Starch 60g/1000ml, L-Malic Acid 0.67g/1000ml	Solution For Infusion	Intravenous Use
Portugal	Fresenius Kabi Pharma Portugal, Lda.	Volulyte 60 mg/ml Solução para Perfusão	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Poly (O-2-Hydroxyethyl) Starch 130/0.4 (Ph.Eur.) 60g/1000ml	Solution For Infusion	Intravenous Use
Portugal	Fresenius Kabi Pharma Portugal, Lda.	Voluven Fresenius 100 mg/ml + 9 mg/ml solução para perfusão	Magnesium Chloride Hexahydrate 0.3gl, Potassium Chloride 0.3gl, Sodium Chloride 6.02gl, Sodium Acetate Trihydrate 4.63gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Fresenius Kabi Pharma Portugal, Lda.	Voluven Fresenius 60 mg/ml + 9 mg/ml solução para perfusão	Sodium Chloride 9g, Hydroxyethyl Starch 130/0.4 60g/l	Solution For Infusion	Intravenous Use
Portugal	B. Braun Melsungen AG	Tetraspan 60 mg/ml solução para perfusão	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Hetastarch 100g/1000ml, Malic Acid 0.67g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml	Solution For Infusion	Intravenous Use
Romania	Fresenius Kabi Romania srl	Volulyte 6%, soluție perfuzabilă	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Romania	Fresenius Kabi Deutschland GmbH	Voluven 60 g/1000 ml soluție perfuzabilă	Sodium Chloride 9g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Romania	B. Braun Melsungen AG	Tetraspan 60 mg/ml	Magnesium Chloride Hexahydrate 0.203g/1000ml, Potassium Chloride 0.298g/1000ml, Sodium Chloride 6.252g/1000ml, Calcium Chloride Dihydrate 0.367g/1000ml, Sodium Acetate Trihydrate 3.266g/1000ml, L-Malic Acid 0.671g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Slovakia	B. Braun Melsungen Ag	Tetraspan	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
			6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Hetastarch 100g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml, L-Malic Acid 0.67g/1000ml		
Slovakia	Fresenius Kabi Deutschland GmbH	Volulyte 6%, infúzny roztok	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Slovakia	Fresenius Kabi s.r.o.	Voluven 10%, infúzny roztok	Sodium Chloride 9g, Hydroxyethyl Starch 130/0.4 100g	Solution For Infusion	Intravenous Use
Slovakia	Fresenius Kabi Deutschland GmbH	Voluven, 6 % infúzny roztok	Sodium Chloride 9g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Slovenia	Fresenius Kabi Austria GmbH	Volulyte 60 mg/ml raztopina za infundiranje	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Slovenia	Fresenius Kabi Deutschland GmbH	Voluven 100 mg/ml raztopina za infundiranje	Sodium Chloride 9g/1000ml, Hydroxyethyl Starch 130/0.4 100g/1000ml	Solution For Infusion	Intravenous Use
Slovenia	Fresenius Kabi Austria GmbH	VOLUVEN 60 mg/ml raztopina za infundiranje	Sodium Chloride 9g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use

Member State in EEA	Marketing authorisation holder	Product Name (in authorisation country)	INN + Strength	Pharmaceutical form	Route of administration
Spain	Fresenius Kabi Deutschland GmbH	Volulyte 6% solución para perfusión	Magnesium Chloride Hexahydrate 0.3g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.02g/1000ml, Sodium Acetate Trihydrate 4.63g/1000ml, Hydroxyethyl Starch 130/0.4 60g/1000ml	Solution For Infusion	Intravenous Use
Spain	Fresenius Kabi Austria GmbH	Voluven 6% Solución para perfusion	Sodium Chloride 9gl, Hydroxyethyl Starch 130/0.4 60gl	Solution For Infusion	Intravenous Use
Spain	B. Braun Melsungen AG	Isohes 6% Solución para perfusión	Magnesium Chloride Hexahydrate 0.2g/1000ml, Potassium Chloride 0.3g/1000ml, Sodium Chloride 6.25g/1000ml, Calcium Chloride Dihydrate 0.37g/1000ml, Hetastarch 60g/1000ml, Sodium Acetate Trihydrate 3.27g/1000ml, L-Malic Acid 0.67g/1000ml	Solution For Infusion	Intravenous Use