

21 April 2023
EMA/48335/2014 corr 6*
Patient Health Protection

For the UK, as from 1st January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI

List of hydroxyethyl starch(HES)-containing medicinal products in the European Union

Name of the product	Marketing Authorisation Holder	Country where product is authorised
PlasmaHES Redibag – Infusionsloesung	Baxter Healthcare GmbH	Austria
Refortan 6% Infusionsflasche	Fresenius Kabi Austria GmbH	Austria
Refortan plus 10% Infusionsflasche	Fresenius Kabi Austria GmbH	Austria
Stabisol 6% Infusionsflasche	Fresenius Kabi Austria GmbH	Austria
Tetraspan 60 mg/ml Infusionsloesung	B. Braun Melsungen AG	Austria
Venofundin 60 mg/ml Infusionsloesung	B. Braun Melsungen AG	Austria
Volulyte 6% Infusionsloesung	Fresenius Kabi Austria GmbH	Austria
Voluven (HES 130/0,4) 6% - Infusionsloesung	Fresenius Kabi Austria GmbH	Austria
Plasmavolume Redibag 6%	Baxter SA	Belgium
Tetraspan 10%	B. Braun Melsungen AG	Belgium
Tetraspan 6%	B. Braun Melsungen AG	Belgium
Venohes 6%	B. Braun Melsungen AG	Belgium
Volulyte 6%	Fresenius Kabi NV	Belgium
Voluven 10%	Fresenius Kabi NV	Belgium
Voluven 6%	Fresenius Kabi NV	Belgium
Hemohe 6%	B. Braun Melsungen AG	Bulgaria
Voluven 6%	Fresenius Kabi Deutschland GmbH	Bulgaria
Voluven 10%	Fresenius Kabi Bulgaria EOOD	Bulgaria
Volulyte 6%	Fresenius Kabi Bulgaria EOOD	Bulgaria
Plasma volume Redibag	Baxter Deutschland GmbH	Bulgaria
Tetraspan 60 mg/ml Solution For Infusion	B. Braun Adria d.o.o.	Croatia
Tetraspan 100 mg/ml Solution For Infusion	B. Braun Adria d.o.o.	Croatia
Volulyte 6% otopina za infuziju	Fresenius Kabi d.o.o.	Croatia
Voluven 6% otopina za infuziju	Fresenius Kabi d.o.o.	Croatia
Volulyte Solution For Infusion 6%	Fresenius Kabi Hellas AE	Cyprus
Voluven Solution For Infusion 10%	Fresenius Kabi Hellas AE	Cyprus
Plasma-Volume-Redibag-6%	Baxter-Czech-spol.-s.r.o.	Czech-Republic
Tetraspan-10%	B. Braun Melsungen AG	Czech-Republic
Tetraspan-6%	B. Braun Melsungen AG	Czech-Republic
Volulyte 6%	Fresenius Kabi Deutschland GmbH	Czech Republic
Voluven 10%	Fresenius Kabi s.r.o.	Czech Republic
Voluven	Fresenius Kabi Deutschland GmbH	Czech Republic
Hesra	Baxter A/S	Denmark
Tetraspan	B. Braun Melsungen	Denmark
Tetraspan	B. Braun Melsungen	Denmark
Venofundin	B. Braun Melsungen	Denmark
Volulyte	Fresenius Kabi AB	Denmark
Voluven	Fresenius Kabi AB	Denmark
Voluven	Fresenius Kabi AB	Denmark
Tetraspan 60 mg/ml	B. Braun Melsungen AG	Estonia
Tetraspan 100 mg/ml	B. Braun Melsungen AG	Estonia
Voluven	Fresenius Kabi Deutschland GmbH	Estonia
Volulyte	Fresenius Kabi Deutschland GmbH	Estonia
Voluforte	Fresenius Kabi Polska Sp.z o.o	Estonia
Volulyte	Fresenius Kabi AB	Finland
Voluven	Fresenius Kabi AB	Finland
Voluven	Fresenius Kabi AB	Finland
ISOVOL 6%, solution pour perfusion	B Braun Melsungen	France
Plasmavolume 6%, solution pour perfusion	Baxter S.A.S.	France
Volulyte 6%, solution pour perfusion	Fresenius Kabi France	France
RESTORVOL 6%, solution pour perfusion	B Braun Melsungen	France
Voluven, solution pour perfusion	Fresenius Kabi France	France
PLASMOHES 6%, solution pour perfusion	AGUETTANT	France

Name of the product	Marketing Authorisation Holder	Country where product is authorised
HEAFUSINE 10%, solution pour perfusion en poche	B Braun Melsungen	France
HEAFUSINE 6%, solution pour perfusion en poche	B Braun Melsungen	France
HYPERHES, solution pour perfusion	Fresenius Kabi France	France
Hemohees 6%	B. Braun Melsungen AG	Germany
Hemohees 10%	B. Braun Melsungen AG	Germany
Venofundin 60 mg/ml Infusionslösung	B. Braun Melsungen AG	Germany
Tetraspan 6% Infusionslösung	B. Braun Melsungen AG	Germany
Tetraspan 10% Infusionslösung	B. Braun Melsungen AG	Germany
Plasma Volume Redibag	Baxter Deutschland GmbH	Germany
Refortan 6%	Berlin-Chemie AG	Germany
Refortan 10%	Berlin-Chemie AG	Germany
Volulyte 6% Infusionslösung	Fresenius Kabi Deutschland GmbH	Germany
Voluven 6% Infusionslösung	Fresenius Kabi Deutschland GmbH	Germany
Haes-Steril 3%	Fresenius Kabi Deutschland GmbH	Germany
Voluven Fresenius 6% Infusionslösung	Fresenius Kabi Deutschland GmbH	Germany
Haes-Steril 10%	Fresenius Kabi Deutschland GmbH	Germany
Volulyte 6% Infusionslösung	Fresenius Kabi Deutschland GmbH	Germany
Haes-Steril 6%	Fresenius Kabi Deutschland GmbH	Germany
Voluven 6% Infusionslösung	Fresenius Kabi Deutschland GmbH	Germany
Voluven 10% Infusionslösung	Fresenius Kabi Deutschland GmbH	Germany
Infukoll HES 6%	Serumwerk Bernburg AG	Germany
Vitafusal 10%	Serumwerk Bernburg AG	Germany
Vitakoll 10%	Serumwerk Bernburg AG	Germany
Infukoll HES 10%	Serumwerk Bernburg AG	Germany
Vitafusal 6%	Serumwerk Bernburg AG	Germany
Vitafusal	Serumwerk Bernburg AG	Germany
VitaHES Infusionslösung	Serumwerk Bernburg AG	Germany
Voluven 6%	Fresenius Kabi Hellas AE	Greece
Voluven 10%	Fresenius Kabi Hellas AE	Greece
Venofundin	Vioser SA	Greece
Volulyte	Fresenius Kabi Hellas AE	Greece
Plasmavolume Redibag	Baxter Hellas Ltd	Greece
Tetraspan	Vioser SA	Greece
Tetraspan	Vioser SA	Greece
Volulyte 6% oldatos infúzió	Fresenius Kabi Deutschland GmbH	Hungary
Voluven 10% oldatos infúzió	Fresenius Kabi Deutschland GmbH	Hungary
Voluven 6% oldatos infúzió	Fresenius Kabi Deutschland GmbH	Hungary
Tetraspan 60 mg/ml	B. Braun Melsungen AG	Hungary
Tetraspan 100 mg/ml	B. Braun Melsungen AG	Hungary
HesRa	Baxter Hungary	Hungary
Tetraspan	B. Braun Melsungen AG	Iceland
Volulyte	Fresenius Kabi Deutschland GmbH	Iceland
Voluven	Fresenius Kabi AB	Iceland
Plasma Volume Redibag 6% Solution For Infusion	Baxter Healthcare Limited	Ireland
EquiHes 60 mg/ml Solution For Infusion, Ecoflac Plus	B. Braun Melsungen AG	Ireland
EquiHes 100 mg/ml Solution For Infusion, Ecoflac Plus	B. Braun Melsungen AG	Ireland
EquiHes 60 mg/ml Solution For Infusion, Ecobag	B. Braun Melsungen AG	Ireland
EquiHes 100 mg/ml Solution For Infusion, Ecobag	B. Braun Melsungen AG	Ireland
Voluven 10% Solution For Infusion (Polyolefine Bag)	Fresenius Kabi Limited	Ireland
Voluven 10% Solution For Infusion (PE Bottle)	Fresenius Kabi Limited	Ireland
Voluven 6% Solution For Infusion (Glass bottle)	Fresenius Kabi Limited	Ireland
Voluven 6% Solution For Infusion (Polyolefine/Freefle x Bag)	Fresenius Kabi Limited	Ireland
Voluven 6% Solution For Infusion (PVC Bag)	Fresenius Kabi Limited	Ireland
Volulyte 6% Solution For Infusion, polyolefine bags	Fresenius Kabi Limited	Ireland
Volulyte 6% Solution For Infusion, glass bottle	Fresenius Kabi Limited	Ireland
Vonten	Fresenius Kabi Italia Srl	Italy
Voluven	Fresenius Kabi Italia Srl	Italy

Name of the product	Marketing Authorisation Holder	Country where product is authorised
Amidolite	B. Braun Melsungen AG	Italy
Tetraspan	B. Braun Melsungen AG	Italy
Tetraspan	B. Braun Melsungen AG	Italy
Plasmavolume	Baxter S.p.A.	Italy
Volulyte	Fresenius Kabi Italia Srl	Italy
Haes-Steril	Fresenius Kabi Deutschland GmbH	Italy
Haes-Steril	Fresenius Kabi Deutschland GmbH	Italy
Voluven 6% Solution For Infusion	Fresenius Kabi Deutschland GmbH	Latvia
Volulyte 6% Solution For Infusion	Fresenius Kabi Deutschland GmbH	Latvia
Tetraspan 60 mg/ml Solution For Infusion	B. Braun Melsungen AG	Latvia
Tetraspan 100 mg/ml Solution For Infusion	B. Braun Melsungen AG	Latvia
Refortan	UAB "Berlin Chemie Menarini Baltic"	Lithuania
Refortan Plus	UAB "Berlin Chemie Menarini Baltic"	Lithuania
Stabisol	UAB "Berlin Chemie Menarini Baltic"	Lithuania
Voluforte	Fresenius Kabi Polska Sp.zo.o.	Lithuania
Volulyte	Fresenius Kabi Deutschland GmbH	Lithuania
Voluven	Fresenius Kabi Deutschland GmbH	Lithuania
Tetraspan	B. Braun Melsungen AG	Lithuania
Tetraspan	B. Braun Melsungen AG	Lithuania
Hemohe 6%	B.Braun Melsungen A.G.	Luxembourg
Hemohe 10%	B.Braun Melsungen A.G.	Luxembourg
Plasma Volume Redibag 6%	Baxter S.A.	Luxembourg
Tetraspan 6%	B. Braun Melsungen A.G.	Luxembourg
Tetraspan 10%	B. Braun Melsungen A.G.	Luxembourg
Venofundin 60 mg/ml	B. Braun Melsungen A.G.	Luxembourg
Volulyte 6%	Fresenius Kabi Deutschland GmbH	Luxembourg
Voluven 6%	Fresenius Kabi Deutschland GmbH	Luxembourg
Volulyte6% Solution For Infusion	Fresenius Kabi Limited	Malta
Plasma Volume Redibag 6% Solution For Infusion	Baxter Healthcare Limited	Malta
Hesra	Baxter AS	Norway
Tetraspan	B. Braun Melsungen AG	Norway
Venofundin	B. Braun Melsungen AG	Norway
Volulyte	Fresenius Kabi Norge AS	Norway
Voluven 6%	Fresenius Kabi Norge AS	Norway
Refortan	Berlin-Chemie AG	Poland
6% Hydroksyetyloskro bia 200/0,5 Baxter	Baxter Polska Sp. z o.o.	Poland
10% Hydroksyetyloskro bia 200/0,5 Baxter	Baxter Polska Sp. z o.o.	Poland
Refortan Forte	Berlin-Chemie AG	Poland
Hemohe 6%	B. Braun Melsungen AG	Poland
Hemohe 10%	B. Braun Melsungen AG	Poland
Tetraspan 60 mg/ml HES roztwór do infuzji	B. Braun Melsungen AG	Poland
Tetraspan 100 mg/ml HES roztwór do infuzji	B. Braun Melsungen AG	Poland
Plasmavolume Redibag	Baxter Polska Sp. z o.o.	Poland
Voluven 10%	Fresenius Kabi Polska Sp. z o.o.	Poland
Voluven	Fresenius Kabi Deutschland GmbH	Poland
Volulyte 6%	Fresenius Kabi Deutschland GmbH	Poland
Voluven Fresenius	Fresenius Kabi Pharma Portugal, Lda	Portugal
Venofundin	B. Braun Melsungen A.G.	Portugal
Volulyte	Fresenius Kabi Pharma Portugal, Lda	Portugal
Tetraspan	B. Braun Melsungen A.G.	Portugal
Tetraspan	B. Braun Melsungen A.G.	Portugal
Plasmavolume Redibag	Baxter Médico- Farmacêutica, Lda.	Portugal
Voluven Fresenius	Fresenius Kabi Pharma Portugal, Lda	Portugal
Vitafusal	S.C. INFOMED FLUIDS S.R.L.	Romania
Voluven 60 g/1000 ml	Fresenius Kabi Deutschland GmbH	Romania
Infohe 60 g/l	S.C. INFOMED FLUIDS S.R.L.	Romania
Infohe 100 g/l	S.C. INFOMED FLUIDS S.R.L.	Romania

Name of the product	Marketing Authorisation Holder	Country where product is authorised
Hemohe 6%	B. Braun Melsungen AG	Romania
Hemohe 10%	B. Braun Melsungen AG	Romania
Haes-Steril 60g/1000 ml	Fresenius Kabi Deutschland GmbH	Romania
Haes-Steril 100 g/1000 ml	Fresenius Kabi Deutschland GmbH	Romania
Venofundin 6 g/100 ml	B. Braun Melsungen AG	Romania
Volulyte 6%	S.C. Fresenius Kabi România S.R.L	Romania
Tetraspan 60 mg/ml	B. Braun Melsungen AG	Romania
Tetraspan 100 mg/ml	B. Braun Melsungen AG	Romania
Plasmavolume Redibag	Baxter Czech spol. s r.o.	Slovak Republic
Tetraspan 10%	B. Braun Melsungen AG	Slovak Republic
Tetraspan 6%	B. Braun Melsungen AG	Slovak Republic
Volulyte 6%, infúzný roztok	Fresenius Kabi Deutschland GmbH	Slovak Republic
Voluven	Fresenius Kabi Deutschland GmbH	Slovak Republic
Voluven 10%	Fresenius Kabi s.r.o.	Slovak Republic
Haes-Steril 60 mg/ml raztopina za infundiranje	Medias International d.o.o.	Slovenia
Plasma Volume Redibag 60 mg/ml raztopina za infundiranje	Baxter d.o.o.	Slovenia
Tetraspan 60 mg/ml raztopina za infundiranje	B.Braun Melsungen AG	Slovenia
Tetraspan 100 mg/ml raztopina za infundiranje	B.Braun Melsungen AG	Slovenia
Volulyte 60 mg/ml raztopina za infundiranje	Medias International d.o.o.	Slovenia
Voluven 100 mg/ml raztopina za infundiranje	Fresenius Kabi Deutschland GmbH	Slovenia
Voluven 60 mg/ml raztopina za infundiranje	Medias International d.o.o.	Slovenia
Voluven 6% Solución Para Perfusión	Fresenius Kabi Deutschland GmbH	Spain
Voluven 10% Solución Para Perfusión	Fresenius Kabi España S.A.	Spain
Hes Hipertonico Fresenius Solución Para Perfusión	Fresenius Kabi Deutschland GmbH	Spain
Volulyte 6% Solución Para Perfusión	Fresenius Kabi Deutschland GmbH	Spain
Isohes 6% Solución Para Perfusión	B. Braun Melsungen AG	Spain
Plasmavolume Redibag Solución Para Perfusión	Baxter S.L.	Spain
Voluven 60 mg/ml Infusionsvätska, lösning	Fresenius Kabi AB	Sweden
Venofundin®	B. Braun Melsungen AG	Sweden
Tetraspan	B. Braun Melsungen AG	Sweden
Tetraspan	B. Braun Melsungen AG	Sweden
Volulyte 60 mg/ml Infusionsvätska, lösning	Fresenius Kabi AB	Sweden
Hesra	Baxter Medical AB	Sweden
Voluven 100 mg/ml Infusionsvätska, lösning	Fresenius Kabi AB	Sweden
Tetraspan 10% g/v, oplossing voor infusie 100 g/l	B. Braun Melsungen AG (Melsungen)	The Netherlands
Tetraspan 6% g/v, oplossing voor infusie 60 g/l	B. Braun Melsungen AG (Melsungen)	The Netherlands
Venofundin 60 mg/ml, oplossing voor intraveneuze infusie	B. Braun Melsungen AG (Melsungen)	The Netherlands
Volulyte 6% oplossing voor infusie	Fresenius Kabi Nederland B.V.	The Netherlands
Voluven, 6% (60 mg/ml) oplossing voor infusie	Fresenius Kabi Nederland B.V.	The Netherlands
Voluven 10% (100 mg/ml)	Fresenius Kabi Nederland B.V.	The Netherlands
Plasma Volume Redibag 6%, Solution For Infusion	Baxter B.V.	The Netherlands

* This annex was previously amended on 26 September 2018.

** These products were withdrawn, hence they have been removed from the list.