



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/723696/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Poly (o-2-hydroxyethyl) Starch

Procedure no.: EMEA/H/N/PSR/S/0009



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Volulyte 6% otopina za infuziju		UP/I-530-09/10-01/379	Fresenius Kabi d.o.o.	Croatia
Volulyte 6%, solution pour perfusion		34009 395 519 4 4, 34009 395 520 2 6, 34009 395 521 9 4, 34009 395 522 5 5, 34009 395 523 1 6, 34009 395 524 8 4, 34009 395 525 4 5, 34009 395 526 0 6, 34009 395 527 7 4, 34009 395 528 3 5, 34009 395 530 8 5, 34009 395 531 4 6	Fresenius Kabi France S.A.S.	France
Volulyte 6% Infusionslösung		64678.00.00	Fresenius Kabi Deutschland GmbH	Germany
Volulyte 6% Infusionslösung	DE/H/0619/001	1-27594	Fresenius Kabi Austria GmbH	Austria
Volulyte 6% Infusionslösung , Volulyte 6% oplossing voor infusie, Volulyte 6% solution pour perfusion	DE/H/0619/001	BE319094, BE319103, BE319112, BE319121	Fresenius Kabi nv/sa	Belgium
Волулайт 6% инфузионен разтвор	DE/H/0619/001	20110163	Fresenius Kabi Bulgaria EOOD	Bulgaria
Volulyte 6%, Διάλυμα για έγχυση	DE/H/0619/001	20656	Fresenius Kabi Deutschland GmbH	Cyprus
Volulyte 6%, infuzní roztok	DE/H/0619/001	75/262/08-C	Fresenius Kabi Deutschland GmbH	Czech Republic
Volulyte, infusionsvæske, opløsning	DE/H/0619/001	38802	Fresenius Kabi AB	Denmark
Volulyte, 6% infusioonilahus	DE/H/0619/001	581708	Fresenius Kabi Deutschland GmbH	Estonia
Volulyte 60 mg/ml infuusioneste, liuos	DE/H/0619/001	21810	Fresenius Kabi AB	Finland
Volulyte 6% Infusionslösung	DE/H/0619/001	64677.00.00	Fresenius Kabi Deutschland GmbH	Germany
Volulyte 6%W/V, Διάλυμα για έγχυση	DE/H/0619/001	63062/12/27-05-2013	Fresenius Kabi Hellas A.E.	Greece

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Volulyte 6% oldatos infúzió	DE/H/0619/001	OGYI-T-20582/01, OGYI-T-20582/02, OGYI-T-20582/03, OGYI-T-20582/04, OGYI-T-20582/05, OGYI-T-20582/06, OGYI-T-20582/07, OGYI-T-20582/08	Fresenius Kabi Deutschland GmbH	Hungary
Volulyte 60 mg/ml innrennslislyf, lausn	DE/H/0619/001	IS/1/06/010/01	Fresenius Kabi AB	Iceland
Volulyte 6% Solution for Infusion	DE/H/0619/001	PA 566/37/1, PA 566/37/2	Fresenius Kabi Limited	Ireland
Volulyte 6% Soluzione per infusione	DE/H/0619/001	038473017, 038473029, 038473031, 038473043, 038473056, 038473068, 038473070, 038473082, 038473094, 038473106, 038473118, 038473120	Fresenius Kabi Italia S.r.l.	Italy
Volulyte 6% šķīdums infūzijām	DE/H/0619/001	08-0103	Fresenius Kabi Deutschland GmbH	Latvia
Volulyte 6% infuzinis tirpalas	DE/H/0619/001	LT/1/08/1161/001, LT/1/08/1161/002, LT/1/08/1161/003, LT/1/08/1161/004, LT/1/08/1161/005, LT/1/08/1161/006, LT/1/08/1161/007, LT/1/08/1161/008, LT/1/08/1161/009, LT/1/08/1161/010, LT/1/08/1161/011, LT/1/08/1161/012	Fresenius Kabi Deutschland GmbH	Lithuania
Volulyte 6% Infusionslösung	DE/H/0619/001	0452/09100052	Fresenius Kabi Deutschland GmbH	Luxembourg

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Volulyte 6% Solution for Infusion	DE/H/0619/001	MA 134 / 00801	Fresenius Kabi Limited	Malta
Volulyte 6% oplossing voor infusie	DE/H/0619/001	RVG 33457	Fresenius Kabi Nederland b.v.	Netherlands
Volulyte 60 mg/ml infusjonsvæske, oppløsning	DE/H/0619/001	05-3865	Fresenius Kabi Norge AS	Norway
Volulyte 6%, roztwór do infuzji	DE/H/0619/001	14844	Fresenius Kabi Deutschland GmbH	Poland
Volulyte 60 mg/ml Solução para Perfusão	DE/H/0619/001	5105556, 5105564, 5105572, 5105606, 5105614, 5105622, 5105630, 5105648, 5105655, 5105663, 5105671, 5105705	Fresenius Kabi Pharma Portugal Lda.	Portugal
Volulyte 6%, soluție perfuzabilă	DE/H/0619/001	1583/2009/01, 1583/2009/02, 1583/2009/03, 1583/2009/04, 1583/2009/05, 1583/2009/06, 1583/2009/07, 1583/2009/08, 1583/2009/09, 1583/2009/10, 1583/2009/11, 1583/2009/12	S.C. Fresenius Kabi România S.R.L.	Romania
Volulyte 6%, infúzny roztok	DE/H/0619/001	76/0106/08-S	Fresenius Kabi Deutschland GmbH	Slovakia

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Volulyte 60 mg/ml raztopina za infundiranje	DE/H/0619/001	5363-I-142/12 (obs), 5363-I1537/08 (obs), H/08/01657/001, H/08/01657/002, H/08/01657/003, H/08/01657/004, H/08/01657/005, H/08/01657/006, H/08/01657/007, H/08/01657/008, H/08/01657/009, H/08/01657/010, H/08/01657/011, H/08/01657/012	Medias International D.O.O.	Slovenia
Volulyte 6% solución para perfusión	DE/H/0619/001	70.228	Fresenius Kabi Deutschland GmbH	Spain
Volulyte 60 mg/ml infusionsvätska, lösning	DE/H/0619/001	23245	Fresenius Kabi AB	Sweden
Volulyte 6% Solution for Infusion	DE/H/0619/001	PL 08828/0174	Fresenius Kabi Limited	United Kingdom
Voluven 10% solución para perfusión		73468	Fresenius Kabi España S.A.U.	Spain
Voluven, 10% (100 mg/ml) Infusionslösung, Voluven, 10% (100 mg/ml) oplossing voor infusie, Voluven, 10% (100 mg/ml) solution pour perfusion	DE/H/1568/001	BE 368934, BE 368943	Fresenius Kabi nv/sa	Belgium
Волувен 10% инфузионен разтвор	DE/H/1568/001	20120381	Fresenius Kabi Bulgaria EOOD	Bulgaria
Voluven 10%, infuzní roztok	DE/H/1568/001	76/417/10-C	Fresenius Kabi s.r.o	Czech Republic

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Voluven, infusionsvæske, opløsning	DE/H/1568/001	43009	Fresenius Kabi AB	Denmark
Voluforte, infusioonilahus	DE/H/1568/001	681710	Fresenius Kabi Polska Sp. z o.o.	Estonia
Voluven 100 mg/ml infuusioneste, liuos	DE/H/1568/001	24831	Fresenius Kabi AB	Finland
Voluven 10 % Infusionslösung	DE/H/1568/001	72143.00.00	Fresenius Kabi Deutschland GmbH	Germany
Voluven 10 % oldatos infúzió	DE/H/1568/001	OGYI-T-8387/12, OGYI-T-8387/13, OGYI-T-8387/14, OGYI-T-8387/15, OGYI-T-8387/16, OGYI-T-8387/17	Fresenius Kabi Deutschland GmbH	Hungary
Voluven 10% Solution for Infusion	DE/H/1568/001	PA0566/020/004, PA0566/020/005	Fresenius Kabi Limited	Ireland
Vonten 10% soluzione per infusione	DE/H/1568/001	040747014, 040747026, 040747038, 040747040, 040747053, 040747065	Fresenius Kabi Italia S.r.l.	Italy
Voluforte 10% infuzinis tirpalas	DE/H/1568/001	LT/1/10/1979/001, LT/1/10/1979/002, LT/1/10/1979/003, LT/1/10/1979/004, LT/1/10/1979/005, LT/1/10/1979/006	Fresenius Kabi Polska Sp. z o.o.	Lithuania
Voluven, 10% (100 mg/ml) oplossing voor infusie	DE/H/1568/001	RVG 102156	Fresenius Kabi Nederland b.v.	Netherlands
Voluven 10%, 10% + 0,9%, roztwór do infuzji	DE/H/1568/001	17196	Fresenius Kabi Polska Sp. z o.o.	Poland
Voluven Fresenius 100 mg/ml + 9 mg/ml solução para perfusão	DE/H/1568/001	5283627, 5283635, 5283643, 5283650, 5283668, 5283676	Fresenius Kabi Pharma Portugal Lda.	Portugal
Voluven 10%, infúzný roztok	DE/H/1568/001	76/0134/10-S	Fresenius Kabi s.r.o	Slovakia

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Voluven 100 mg/ml raztopina za infundiranje	DE/H/1568/001	5363-I-1906/10 (obs), 5363-I-1907/10 (obs), 5363-I-1908/10 (obs), 5363-I-1909/10 (obs), 5363-I-1910/10 (obs), 5363-I-1911/10 (obs), H/10/01658/001, H/10/01658/002, H/10/01658/003, H/10/01658/004, H/10/01658/005, H/10/01658/006	Fresenius Kabi Deutschland GmbH	Slovenia
Voluven, 100 mg/ml infusionsvätska, lösning	DE/H/1568/001	26753	Fresenius Kabi AB	Sweden
Voluven 10% Solution for Infusion	DE/H/1568/001	PL 08828/0207	Fresenius Kabi Limited	United Kingdom
Волувен 6% + 0,9% инфузионен разтвор		20020810	Fresenius Kabi Deutschland GmbH	Bulgaria
Voluven 6% otopina za infuziju		HR/H/651961342, UP/I-530-09/09-02/366 (obs)	Fresenius Kabi d.o.o.	Croatia
Voluven, 6% infuzní roztok		75/234/01-C	Fresenius Kabi Deutschland GmbH	Czech Republic
Voluven infusioonilahus		391102	Fresenius Kabi Deutschland GmbH	Estonia
Voluven, solution pour perfusion		367 403-5, 367 404-1	Fresenius Kabi France S.A.S.	France
Voluven 6 % Infusionslösung		42093.00.00	Fresenius Kabi Deutschland GmbH	Germany
Voluven 6 % oldatos infúzió		OGYI-T-8387/02, OGYI-T-8387/03, OGYI-T-8387/04, OGYI-T-8387/05, OGYI-T-8387/06, OGYI-T-8387/08, OGYI-T-8387/09, OGYI-T-8387/10	Fresenius Kabi Deutschland GmbH	Hungary

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Voluven 6% šķīdums infūzijām		03-0177	Fresenius Kabi Deutschland GmbH	Latvia
Voluven 6 % infuzinis tirpalas		LT/1/02/2879/001, LT/1/02/2879/002, LT/1/02/2879/003, LT/1/02/2879/004, LT/1/02/2879/005, LT/1/02/2879/006, LT/1/02/2879/007, LT/1/02/2879/008, LT/1/02/2879/009, LT/1/02/2879/010, LT/1/02/2879/011, LT/1/02/2879/012, LT/1/02/2879/013, LT/1/02/2879/014, LT/1/02/2879/015, LT/1/02/2879/016, LT/1/02/2879/017, LT/1/02/2879/018	Fresenius Kabi Deutschland GmbH	Lithuania
VOLUVEN, (60 mg + 9 mg)/ml, roztwór do infuzji		9370	Fresenius Kabi Deutschland GmbH	Poland
Voluven 60 g/1000 ml soluție perfuzabilă		864/2008/01, 864/2008/02, 864/2008/03, 864/2008/04, 864/2008/05, 864/2008/06, 864/2008/07, 864/2008/08, 864/2008/09, 864/2008/10, 864/2008/11, 864/2008/12, 864/2008/13, 864/2008/14, 864/2008/15, 864/2008/16, 864/2008/17	Fresenius Kabi Deutschland GmbH	Romania
Voluven		76/0023/03-S	Fresenius Kabi Deutschland GmbH	Slovakia

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
VOLUVEN 60 mg/ml raztopina za infundiranje		5363-I-781/14 (obs), 5363-I-782/14 (obs), H/02/01994/001, H/02/01994/002	Medias International D.O.O.	Slovenia
Voluven (HES 130/0,4) 6% - Infusionslösung	DE/H/0223/001	1-23687	Fresenius Kabi Austria GmbH	Austria
Voluven, 6% (60 mg/ml) Infusionslösung, Voluven, 6% (60 mg/ml) oplossing voor infusie, Voluven, 6% (60 mg/ml) solution pour perfusion	DE/H/0223/001	BE215564, BE215573, BE215582, BE215591, BE215625, BE215634	Fresenius Kabi nv/sa	Belgium
Voluven, infusionsvæske, opløsning	DE/H/0223/001	31342	Fresenius Kabi AB	Denmark
Voluven 60 mg/ml infuusioneste, liuos	DE/H/0223/001	15390	Fresenius Kabi AB	Finland
Voluven Fresenius; 6 % Infusionslösung	DE/H/0223/001	45010.00.00	Fresenius Kabi Deutschland GmbH	Germany
Voluven 6% διάλυμα για έγχυση	DE/H/0223/001	9010/2-2-2017	Fresenius Kabi Hellas A.E.	Greece
Voluven 6%. Innrennsliislyf, lausn.	DE/H/0223/001	IS/1/00/002/01	Fresenius Kabi AB	Iceland
Voluven 6% Solution for Infusion	DE/H/0223/001	PA 566/20/1, PA 566/20/2, PA 566/20/3	Fresenius Kabi Limited	Ireland
Voluven soluzione per infusione al 6%	DE/H/0223/001	034660011, 034660023, 034660035, 034660047, 034660050, 034660062, 034660098, 034660100, 034660276, 034660288, 034660290, 034660302	Fresenius Kabi Italia S.r.l.	Italy
Voluven 6 % Infusionslösung	DE/H/0223/001	0452/05018652	Fresenius Kabi Deutschland GmbH	Luxembourg

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the Member State	Member State where the product is authorised
Voluven, 6% (60 mg/ml) oplossing voor infusie	DE/H/0223/001	RVG 25169	Fresenius Kabi Nederland b.v.	Netherlands
Voluven 60 mg/ml infusjonsvæske, oppløsning	DE/H/0223/001	00-70	Fresenius Kabi Norge AS	Norway
Voluven Fresenius 60 mg/ml + 9 mg/ml solução para perfusão	DE/H/0223/001	3369089, 3369188, 3369287, 3369386, 3369485, 3369584, 3369881, 3369980, 4765988, 4766085, 4766184, 4766283, 4766382, 4766481, 4766580, 4766689, 4767182, 4767281, 4767380, 4767489, 5459920, 5459938, 5459946, 5459953	Fresenius Kabi Pharma Portugal Lda.	Portugal
Voluven 60 mg/ml, infusionsvätska, lösning	DE/H/0223/001	16106	Fresenius Kabi AB	Sweden
Voluven 6% solution for infusion	DE/H/0223/001	PL 08828/0145	Fresenius Kabi Limited	United Kingdom
Voluven 6 %; Infusionslösung	DE/H/272/001	44943.00.00	Fresenius Kabi Deutschland GmbH	Germany
Voluven 6% Solución para perfusión	DE/H/272/001	64.001	Fresenius Kabi Deutschland GmbH	Spain
HAES-steril 10% Infusionslösung		417.00.00	Fresenius Kabi Deutschland GmbH	Germany
HAES-steril 3%		7978.00.00	Fresenius Kabi Deutschland GmbH	Germany
HAES- steril "Fresenius" (HES 200/0,5) 6 % - Infusionslösung		1-22029	Fresenius Kabi Austria GmbH	Austria
HAES-steril 6% Infusionslösung		417.01.00	Fresenius Kabi Deutschland GmbH	Germany
HyperHES, solution pour perfusion	DE/H/0295/001	NL 26789	Fresenius Kabi France S.A.S.	France
HES Hipertónico Fresenius, solución para perfusión	DE/H/0295/001	65.021	Fresenius Kabi Deutschland GmbH	Spain