



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 July 2015
EMA/382258/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: hydroxyethyl starch

Procedure no.: PSUSA/00001694/201501



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Equihes Ecobag	SE/H/0609/001	PA 736/24/3	B. Braun Melsungen Ag Art 57	IE
Equihes Ecoflac Plus	SE/H/0609/001	PA 736/24/1	B. Braun Melsungen Ag Art 57	IE
Haes- Steril		1-22029	Fresenius Kabi Austria Gmbh Graz	AT
Haes-Steril		2428282,2428381,2520187,2520286,3590783,3590882	Fresenius Kabi Pharma Portugal Lda.	PT
Hesra	DE/H/1210/001	07-5185	Serumwerk Bernburg Ag	NO
Hesra	DE/H/1210/001	24034	Serumwerk Bernburg Ag	FI
Hesra	DE/H/1210/001	42013	Serumwerk Bernburg Ag	DK
Hesra	DE/H/1210/001MR	25966	Serumwerk Bernburg Ag	SE
Hyperhaes	DE/H/295/01	1-24986	Fresenius Kabi Austria Gmbh Graz	AT
Hyperhaes	DE/H/295/01	16534	Fresenius Kabi Ab Uppsala, Sweden	FI
Hyperhaes	DE/H/295/01	48783.00.00	Fresenius Kabi Deutschland Gmbh Bad Homburg	DE
Plasma Volume	DE/H/1210/001	31830/08/03-02-2009	Baxter Hellas	GR
Plasma Volume Redibag	DE/H/1210/001	70490	Baxter, S.L.	ES
Plasmavolume Redibag	DE/H/1210/001	15420	Serumwerk Bernburg Ag	PL
Plasmavolume Redibag	DE/H/1210/001	5139241	Serumwerk Bernburg Ag	PT
Plasmavolume Redibag	DE/H/1210/001	68113.00.00	Serumwerk Bernburg Ag	DE
Plasmavolume Redibag	DE/H/1210/001MR	70.490	Serumwerk Bernburg Ag	ES
Plasmavolume Redibag	DE/H/1210/001MR	AIC NR 038809012/M	Serumwerk Bernburg Ag	IT
Refortan		1-19044	Fresenius Kabi Austria Gmbh Graz	AT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Refortan Plus		1-18358	Fresenius Kabi Austria Gmbh Graz	AT
Stabisol		1-18268	Fresenius Kabi Austria Gmbh Graz	AT
Tetraspan		5519/2013/01	B. Braun Melsungen Ag Art 57	RO
Tetraspan		5519/2013/02	B. Braun Melsungen Ag Art 57	RO
Tetraspan		5519/2013/03	B. Braun Melsungen Ag Art 57	RO
Tetraspan		5519/2013/04	B. Braun Melsungen Ag Art 57	RO
Tetraspan	SE/H/0609/001	037596018	B. Braun Melsungen Ag Art 57	IT
Tetraspan	SE/H/0609/001	037596032	B. Braun Melsungen Ag Art 57	IT
Tetraspan	SE/H/0609/001	12809	B. Braun Melsungen Ag Art 57	PL
Tetraspan	SE/H/0609/001	44431	B. Braun Melsungen Ag Art 57	GR
Tetraspan	SE/H/0609/001	527706	B. Braun Melsungen Ag Art 57	EE
Tetraspan	SE/H/0609/001	5363-I-851/14	B. Braun Melsungen Ag Art 57	SI
Tetraspan	SE/H/0609/001	5363-I-852/14	B. Braun Melsungen Ag Art 57	SI
Tetraspan	SE/H/0609/001	5992789	B. Braun Melsungen Ag Art 57	PT
Tetraspan	SE/H/0609/001	5992987	B. Braun Melsungen Ag Art 57	PT
Tetraspan	SE/H/0609/001	5993183	B. Braun Melsungen Ag Art 57	PT
Tetraspan	SE/H/0609/001	PL 03551/0106	B. Braun Melsungen Ag Art 57	GB
Tetraspan	SE/H/609/01MR	037596057	B. Braun Melsungen Ag Art 57	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Vitafusal 6%	DE/H/1210/001MR	1-27873	Serumwerk Bernburg Ag	AT
Vitafusal®		60252.00.00	Serumwerk Bernburg Ag	DE
Vitafusal® 10%		71020.00.00	Serumwerk Bernburg Ag	DE
Vitafusal® 6%		66030.00.00	Serumwerk Bernburg Ag	DE
Vitahes®	DE/H/1670/001MR	60257.00.00	Serumwerk Bernburg Ag	DE
Volulyte	DE/H/0619/01/DC	1-27594	Fresenius Kabi Austria Gmbh Graz	AT
Volulyte	DE/H/0619/01/DC	5105556	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105564	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105572	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105606	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105614	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105622	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105630	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105648	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105655	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105663	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105671	Fresenius Kabi Pharma Portugal Lda.	PT
Volulyte	DE/H/0619/01/DC	5105705	Fresenius Kabi Pharma Portugal Lda.	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Voluven		864/2008/01	Fresenius Kabi Deutschland Gmbh Bad Homburg	RO
Voluven		864/2008/13	Fresenius Kabi Deutschland Gmbh Bad Homburg	RO
Voluven		864/2008/14	Fresenius Kabi Deutschland Gmbh Bad Homburg	RO
Voluven		864/2008/15	Fresenius Kabi Deutschland Gmbh Bad Homburg	RO
Voluven		864/2008/16	Fresenius Kabi Deutschland Gmbh Bad Homburg	RO
Voluven		864/2008/17	Fresenius Kabi Deutschland Gmbh Bad Homburg	RO
Voluven		9370	Fresenius Kabi Deutschland Gmbh Bad Homburg	PL
Voluven		LT/1/02/2879/001	Fresenius Kabi Deutschland Gmbh Bad Homburg	LT
Voluven	DE/H/1568/001/DC	17196	Fresenius Kabi Polska Sp. Z O.O.	PL
Voluven	DE/H/1568/001/DC	20798	Fresenius Kabi Hellas A.E.	CY
Voluven	DE/H/1568/001/DC	26753	Fresenius Kabi Ab Uppsala, Sweden	SE
Voluven	DE/H/1568/001/DC	5283627	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/1568/001/DC	5283635	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/1568/001/DC	5283643	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/1568/001/DC	5283650	Fresenius Kabi	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
			Pharma Portugal Lda.	
Voluven	DE/H/1568/001/DC	5283668	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/1568/001/DC	5283676	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/1568/001/DC	5363-I-1906/10	Fresenius Kabi Deutschland Gmbh Bad Homburg	SI
Voluven	DE/H/1568/001/DC	5363-I-1907/10	Fresenius Kabi Deutschland Gmbh Bad Homburg	SI
Voluven	DE/H/1568/001/DC	5363-I-1908/10	Fresenius Kabi Deutschland Gmbh Bad Homburg	SI
Voluven	DE/H/1568/001/DC	5363-I-1909/10	Fresenius Kabi Deutschland Gmbh Bad Homburg	SI
Voluven	DE/H/1568/001/DC	5363-I-1910/10	Fresenius Kabi Deutschland Gmbh Bad Homburg	SI
Voluven	DE/H/1568/001/DC	5363-I-1911/10	Fresenius Kabi Deutschland Gmbh Bad Homburg	SI
Voluven	DE/H/1568/001/DC	72143.00.00	Fresenius Kabi Deutschland Gmbh Bad Homburg	DE
Voluven	DE/H/1568/001/DC	75301/5-11-2010	Fresenius Kabi Hellas A.E.	GR
Voluven	DE/H/1568/001/DC	BE 368934, BE 368943	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/1568/001/DC	BE 368943	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/1568/001/DC	OGYI-T-8387/12	Fresenius Kabi Deutschland Gmbh Bad Homburg	HU
Voluven	DE/H/1568/001/DC	OGYI-T-8387/13	Fresenius Kabi Deutschland Gmbh	HU

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
			Bad Homburg	
Voluven	DE/H/1568/001/DC	OGYI-T-8387/14	Fresenius Kabi Deutschland Gmbh Bad Homburg	HU
Voluven	DE/H/1568/001/DC	OGYI-T-8387/15	Fresenius Kabi Deutschland Gmbh Bad Homburg	HU
Voluven	DE/H/1568/001/DC	OGYI-T-8387/16	Fresenius Kabi Deutschland Gmbh Bad Homburg	HU
Voluven	DE/H/1568/001/DC	OGYI-T-8387/17	Fresenius Kabi Deutschland Gmbh Bad Homburg	HU
Voluven	DE/H/1568/001/DC	RVG 102156	Fresenius Kabi Nederland B.V.	NL
Voluven	DE/H/223/01	00-70	Fresenius Kabi Norge As Halden	NO
Voluven	DE/H/223/01	034660011/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660023/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660035/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660047/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660050/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660062/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660098/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660100/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660276/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660288/M	Fresenius Kabi Italia	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
			S.R.L.	
Voluven	DE/H/223/01	034660290/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	034660302/M	Fresenius Kabi Italia S.R.L.	IT
Voluven	DE/H/223/01	1-23687	Fresenius Kabi Austria Gmbh Graz	AT
Voluven	DE/H/223/01	16106	Fresenius Kabi Ab Uppsala, Sweden	SE
Voluven	DE/H/223/01	3369089	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369188	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369287	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369386	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369485	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369584	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369881	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	3369980	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	38024/12-6-2007	Fresenius Kabi Hellas A.E.	GR
Voluven	DE/H/223/01	45010.00.00	Fresenius Kabi Deutschland Gmbh Bad Homburg	DE
Voluven	DE/H/223/01	4765988 3369-089-188-287-386-485-584-683-782-881-980	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4766085	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4766184	Fresenius Kabi Pharma Portugal Lda.	PT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Voluven	DE/H/223/01	4766283	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4766382	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4766481	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4766580	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4766689	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4767182	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4767281	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4767380	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	4767489	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	5459920	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	5459938	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	5459946	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	5459953	Fresenius Kabi Pharma Portugal Lda.	PT
Voluven	DE/H/223/01	BE215564	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/223/01	BE215573	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/223/01	BE215582	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/223/01	BE215591	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/223/01	BE215625	Fresenius Kabi N.V./S.A. Belgium	BE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Voluven	DE/H/223/01	BE215634	Fresenius Kabi N.V./S.A. Belgium	BE
Voluven	DE/H/223/01	RVG 25169	Fresenius Kabi Nederland B.V.	NL
Voluven	DE/H/272/001	44943.00.00	Fresenius Kabi Deutschland Gmbh Bad Homburg	DE
Voluven	DE/H/272/001	64.001	Fresenius Kabi Deutschland Gmbh Bad Homburg	ES
HAES-steril 10%		417.00.00	Fresenius Kabi Deutschland	DE
HAES-steril 6%		417.01.00	Fresenius Kabi Deutschland	DE
Voluven 6%		42093.00.00	Fresenius Kabi Deutschland	DE
HAES-steril 3%		7978.00.00	Fresenius Kabi Deutschland	DE
Hyperhaes		65.021	Fresenius Kabi Spain	ES
Hyperhaes	DE/H/295/001	360 517-5, 360 518-1, 360 519-8	Fresenius Kabi France S.A.S.	FR
Hyperhaes	DE/H/295/001	4073383, 4073482, 4073581	Fresenius Kabi Portugal LDA.	PT
Vitalfusol 6%-infusionlosung	DE/H/1210/001MR	1-27873	Serumwerk Bernburg Ag	AT
Infukoll HES 6%		3000176.00.00	Serumwerk Bernburg Ag	DE
Infukoll HES 10%		3000176.01.00	Serumwerk Bernburg Ag	DE
Voluven	DE/H/0223/001	31342	Fresenius Kabi AB	DK
Voluven	DE/H/0223/001	15390	Fresenius Kabi AB	FI
Voluven	DE/H/0223/001	PA 566/20/1	Fresenius Kabi Limited	IE
Voluven	DE/H/0223/001	IS-1/00/002/02	Fresenius Kabi AB	IS

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Voluven	DE/H/0223/001	0452/05018652	Fresenius Kabi Deutschland	LU
Voluven	DE/H/0223/001	PL 08828/0145	Fresenius Kabi Limited	GB
Voluven	DE/H/1568/001/DC	20798	Fresenius Kabi Bulgaria EOOD	BG
Voluven	DE/H/1568/001/DC	43009	Fresenius Kabi AB	DK
Voluven	DE/H/1568/001/DC	681710	Fresenius Kabi Polska Sp. Z O.O.	ET
Voluven	DE/H/1568/001/DC	24831	Fresenius kabi AB	FI
Voluven	DE/H/1568/001/DC	PA0566/020/004, PA0566/020/005	Fresenius Kabi Ltd	IE
Voluven	DE/H/1568/001/DC	040747014/M,026,038,040,053,065	Fresenius Kabi Italy S.r.l	IT
Voluven	DE/H/1568/001/DC	LT/1/10/1979/001-006	Fresenius Kabi Polska Sp. Z O.O.	LT
Voluven 60 mg/ml raztopina za infundiranje		5363-I-781/14 5363-I-782/14	Medias International d.o.o.	SL