



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2015
EMA/546145/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: human coagulation factor VIII (antihemophilic factor A)

Procedure no.: PSUSA/00001620/201411



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
Aafact		RVG17121	Sanquin	NL
Amofil		10424	Sanquin	NL
Beriate	DE/H/0483/001	2630689	Csl Behring Gmbh	PT
Beriate	DE/H/0483/002	2630788	Csl Behring Gmbh	PT
Beriate	DE/H/0483/003	2630887	Csl Behring Gmbh	PT
Beriate	DE/H/0483/001	10505A/98-1	Csl Behring Gmbh	DE
Beriate	DE/H/0483/001	2-00213	Csl Behring Gmbh	AT
Beriate	DE/H/0483/004		Csl Behring Gmbh	PT
Beriate	DE/H/0483/001	63.010	Csl Behring Gmbh	ES
Beriate	DE/H/0483/002	10505A/98-2	Csl Behring Gmbh	DE

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
Beriate	DE/H/0483/002	2-00413	Csl Behring Gmbh	AT
Beriate	DE/H/0483/002	63.023	Csl Behring Gmbh	ES
Beriate	DE/H/0483/003	10505A/98-3	Csl Behring Gmbh	DE
Beriate	DE/H/0483/003		Csl Behring Gmbh	AT
Beriate	DE/H/0483/001		Csl Behring Gmbh	PL
Beriate	DE/H/0483/003	63.009	Csl Behring Gmbh	ES
Beriate	DE/H/0483/002		Csl Behring Gmbh	PL
Beriate	DE/H/0483/004	10505A/98-4	Csl Behring Gmbh	DE
Beriate	DE/H/0483/004		Csl Behring Gmbh	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
Beriate	DE/H/0483/003		Csl Behring Gmbh	PL
Beriate	DE/H/0483/004		Csl Behring Gmbh	PL
Beriate	DE/H/0483/001	033657014/M	Csl Behring Gmbh	IT
Beriate	DE/H/0483/004	76960	Csl Behring Gmbh	ES
Beriate	DE/H/0483/002	033657026/M	Csl Behring Gmbh	IT
Beriate	DE/H/0483/003	033657038	Csl Behring Gmbh	IT
Beriate	DE/H/0483/004	033657040	Csl Behring Gmbh	IT
Beriate	DE/H/0483/001		Csl Behring Gmbh	HU
Beriate	DE/H/0483/002		Csl Behring 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
Beriate	DE/H/0483/003		Csl Behring Gmbh	HU
Beriate	DE/H/0483/004		Csl Behring Gmbh	HU
Beriate	DE/H/0483/001		Csl Behring Gmbh	HR
Beriate	DE/H/0483/002		Csl Behring Gmbh	HR
Beriate	DE/H/0483/003		Csl Behring Gmbh	HR
Beriate	DE/H/0483/004		Csl Behring Gmbh	HR
Beriate	DE/H/0483/001		Csl Behring Gmbh	CZ
Beriate	DE/H/0483/002		Csl Behring Gmbh	CZ
Beriate	DE/H/0483/003		Csl Behring Gmbh	CZ

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
Beriate	DE/H/0483/004		Csl Behring Gmbh	CZ
Beriate	DE/H/0483/001	II-28286	Csl Behring Gmbh	BG
Beriate	DE/H/0483/002	II-28287	Csl Behring Gmbh	BG
Beriate	DE/H/0483/003	II-28288	Csl Behring Gmbh	BG
Beriate	DE/H/0483/004	II-28289	Csl Behring Gmbh	BG
Beriate	DE/H/0483/001		Csl Behring Gmbh	RO
Beriate	DE/H/0483/002		Csl Behring Gmbh	RO
Beriate	DE/H/0483/003		Csl Behring Gmbh	RO
Beriate	DE/H/0483/004		Csl Behring Gmbh	RO

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
Beriate	DE/H/0483/001		Csl Behring Gmbh	SK
Beriate	DE/H/0483/002		Csl Behring Gmbh	SK
Beriate	DE/H/0483/003		Csl Behring Gmbh	SK
Beriate	DE/H/0483/004		Csl Behring Gmbh	SK
Beriate	DE/H/0483/001		Csl Behring Gmbh	SI
Beriate	DE/H/0483/002		Csl Behring Gmbh	SI
Beriate	DE/H/0483/003		Csl Behring Gmbh	SI
Beriate	DE/H/0483/004		Csl Behring Gmbh	SI
EMOCLOT		UP/I-530-09/09-01/155	Jasika d.o.o	HR

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
EMOCLOT		UP/I-530-09/09-01/156	Jasika d.o.o	HR
Emoclot		023564216	Kedrion Spa	IT
Emoclot		023564228	Kedrion Spa	IT
Emoclot		9893	Kedrion Spa	PL
Emoclot		9894	Kedrion Spa	PL
Emoclot		II-5837/17.09.2009	Kedrion Spa	BG
Emoclot D.I.		2908986	Kedrion Spa	PT
Emoclot D.I.		3071180	Kedrion Spa	PT
Factane		2006018366	Lfb Biomedicaments	LU

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Factane		2006018367	Lfb Biomedicaments	LU
Factane		34009 562 115 5 5	Lfb Biomedicaments	FR
Factane		34009 562 116 1 6	Lfb Biomedicaments	FR
Factane		34009 562 117 8 4	Lfb Biomedicaments	FR
Factane		34009 585 200 9 9	Lfb Biomedicaments	FR
Factane		34009 585 201 5 0	Lfb Biomedicaments	FR
Factane		4018289	Lfb Biomedicaments	PT
Factane		4018388	Lfb Biomedicaments	PT
Faktor Viii Sdh		16844.00.00	Intersero Gmbh	DE

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
Faktor Viii Sdh		16844.01.00	Intersero Gmbh	DE
Faktor Viii Sdh		16844.02.00	Intersero Gmbh	DE
Haemoctin	DE/H/478/001	OGYI-T-2110/02	Biotest Hungaria Kft.	HU
Haemoctin	DE/H/478/002	OGYI-T-2110/01	Biotest Hungaria Kft.	HU
Haemoctin	DE/H/478/003	OGYI-T-2110/03	Biotest Hungaria Kft.	HU
Haemoctin	DE/H/0478/001	70007	Biotest Pharma Gmbh	ES
Haemoctin	DE/H/0478/002	70008	Biotest Pharma Gmbh	ES
Haemoctin	DE/H/0478/003	70009	Biotest Pharma Gmbh	ES
Haemoctin	DE/H/478/001	038541013	Biotest Pharma Gmbh	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
Haemoctin	DE/H/478/001	101595	Biotest Pharma Gmbh	NL
Haemoctin	DE/H/478/001	17878	Biotest Pharma Gmbh	PL
Haemoctin	DE/H/478/001	5295001	Biotest Pharma Gmbh	PT
Haemoctin	DE/H/478/001	PL 04500/0009	Biotest Pharma Gmbh	GB
Haemoctin	DE/H/478/002	038541025	Biotest Pharma Gmbh	IT
Haemoctin	DE/H/478/002	101596	Biotest Pharma Gmbh	NL
Haemoctin	DE/H/478/002	17879	Biotest Pharma Gmbh	PL
Haemoctin	DE/H/478/002	5295019	Biotest Pharma Gmbh	PT
Haemoctin	DE/H/478/002	PL 04500/0009	Biotest Pharma Gmbh	GB

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
Haemoctin	DE/H/478/003	038541037	Biotest Pharma Gmbh	IT
Haemoctin	DE/H/478/003	101597	Biotest Pharma Gmbh	NL
Haemoctin	DE/H/478/003	17880	Biotest Pharma Gmbh	PL
Haemoctin	DE/H/478/003	5295027	Biotest Pharma Gmbh	PT
Haemoctin	DE/H/478/003	PL 04500/0010	Biotest Pharma Gmbh	GB
Haemoctin	DE/H/478/001	78930/11/21-2-2012	Vianex S.A.	GR
Haemoctin	DE/H/478/002	79689/11/21-2-2012	Vianex S.A.	GR
Haemoctin	DE/H/478/003	12624/16-2-2012	Vianex S.A.	GR
Haemoctin Sdh	DE/H/478/001	2-00375	Biotest Austria Gmbh	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
Haemoctin Sdh	DE/H/478/002	2-00375	Biotest Austria Gmbh	AT
Haemoctin Sdh	DE/H/478/003	2-00376	Biotest Austria Gmbh	AT
Haemoctin Sdh		LT/1/96/1260/001	Biotest Pharma Gmbh	LT
Haemoctin Sdh		LT/1/96/1260/002	Biotest Pharma Gmbh	LT
Haemoctin Sdh		LT/1/96/1260/003	Biotest Pharma Gmbh	LT
Haemoctin Sdh	DE/H/478/001	2868/2010/01	Biotest Pharma Gmbh	RO
Haemoctin Sdh	DE/H/478/001	MA008/00101	Biotest Pharma Gmbh	MT
Haemoctin Sdh	DE/H/478/002	2869/2010/01	Biotest Pharma Gmbh	RO
Haemoctin Sdh	DE/H/478/002	MA008/00102	Biotest Pharma Gmbh	MT

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
Haemoctin Sdh	DE/H/478/003	2870/2010/01	Biotest Pharma Gmbh	RO
Haemoctin Sdh	DE/H/478/003	MA008/00101	Biotest Pharma Gmbh	MT
Haemoctin Sdh 1000	DE/H/0478/003	16/139/92-C/C	Biotest Pharma Gmbh	CZ
Haemoctin Sdh 250	DE/H/0478/001	16/139/92-A/C	Biotest Pharma Gmbh	CZ
Haemoctin Sdh 500	DE/H/0478/002	16/139/92-B/C	Biotest Pharma Gmbh	CZ
HumacLOT		OGYI-T-22285/01	Human Bioplasma Manufacturing And Trading Llc	HU
HumacLOT		OGYI-T-22285/02	Human Bioplasma Manufacturing And Trading Llc	HU
Humafactor-8		OGYI-T-4846/01	Human Bioplasma Manufacturing And Trading Llc	HU
Humafactor-8		OGYI-T-4846/02	Human Bioplasma Manufacturing And Trading Llc	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
Humafactor-8		OGYI-T-4846/03	Human Bioplazma Manufacturing And Trading Llc	HU
Klott		041649017	Kedrion Spa	IT
Klott		041649029	Kedrion Spa	IT
Octafil	SE/H/1070/001-002	18523	Octapharma Ab	FI
Octafil	SE/H/1070/001-002	18524	Octapharma Ab	FI
Octafil Low	SE/H/1070/03-04		Octapharma AB	FI
Octanate		UP/I-530-09-12-02-379 (250 IU)	Jana Pharm D.O.O.	HR
Octanate		UP/I-530-09-12-02-381 (1000 IU)	Jana Pharm D.O.O.	HR
Octanate		UP/I-530-09-12-05-380 (500 IU)	Jana Pharm D.O.O.	HR

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
Octanate		6045	Octapharma (Ip)-Ltd.	BG
Octanate		OGYI-T-6840/01 (1000 IU)	Octapharma (Ip)-Ltd.	HU
Octanate		OGYI-T-6840/02 (250 IU)	Octapharma (Ip)-Ltd.	HU
Octanate		OGYI-T-6840/03 (500 IU)	Octapharma (Ip)-Ltd.	HU
Octanate	SE/H/1070/001	17548	Octapharma (Ip)-Ltd.	PL
Octanate	SE/H/1070/001	5363-I-1273/11	Octapharma (Ip)-Ltd.	SI
Octanate	SE/H/1070/001	5363-I-1274/11	Octapharma (Ip)-Ltd.	SI
Octanate	SE/H/1070/001-002	05-0047 (250 IU)	Octapharma (Ip)-Ltd.	LV
Octanate	SE/H/1070/001-002	05-0048 (500 IU)	Octapharma (Ip)-Ltd.	LV

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
Octanate	SE/H/1070/001-002	05-0049 (1000 IU)	Octapharma (Ip)-Ltd.	LV
Octanate	SE/H/1070/001-002	20061	Octapharma (Ip)-Ltd.	CY
Octanate	SE/H/1070/001-002	20062	Octapharma (Ip)-Ltd.	CY
Octanate	SE/H/1070/001-002	3371-2011-02 (500 IU)	Octapharma (Ip)-Ltd.	RO
Octanate	SE/H/1070/001-002	3372-2011-01 (1000 IU)	Octapharma (Ip)-Ltd.	RO
Octanate	SE/H/1070/001-002	LT/1/05/0261/001 (250 IU)	Octapharma (Ip)-Ltd.	LT
Octanate	SE/H/1070/001-002	LT/1/05/0261/002 (500 IU)	Octapharma (Ip)-Ltd.	LT
Octanate	SE/H/1070/001-002	LT/1/05/0261/003 (1000 IU)	Octapharma (Ip)-Ltd.	LT
Octanate	SE/H/1070/002	17549	Octapharma (Ip)-Ltd.	PL

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
Octanate	SE/H/1070/002	5363-I-1275/11	Octapharma (Ip)-Ltd.	SI
Octanate	SE/H/1070/002	75/004/00-C	Octapharma (Ip)-Ltd.	CZ
Octanate	SE/H/1070/003-004	15-0021	Octapharma (Ip)-Ltd.	LV
Octanate	SE/H/1070/003-004	15-0022	Octapharma (Ip)-Ltd.	LV
Octanate	SE/H/1070/003-004	LT/1/05/0261/004	Octapharma (Ip)-Ltd.	LT
Octanate	SE/H/1070/003-004	LT/1/05/0261/005	Octapharma (Ip)-Ltd.	LT
Octanate		6044	Octapharma (Ip)-Ltd.	BG
Octanate	SE/H/1070/001	16/410/91-B/C	Octapharma (Ip)-Ltd.	CZ
Octanate	SE/H/1070/01-02	MA754/00401	Octapharma (Ip)-Ltd.	MT

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
Octanate	SE/H/1070/01-02	MA754/00402	Octapharma (Ip)-Ltd.	MT
Octanate	SE/H/1070/01-02	3372/2011/01	Octapharma (Ip)-Ltd.	RO
Octanate		398702 (500 IU)	Octapharma Ab	EE
Octanate		398802	Octapharma Ab	EE
Octanate	SE/H/1070/001	21464	Octapharma Ab	SE
Octanate	SE/H/1070/001-002	35521	Octapharma Ab	DK
Octanate	SE/H/1070/001-002	35522	Octapharma Ab	DK
Octanate	SE/H/1070/002	21465	Octapharma Ab	SE
Octanate		04-2451 (500 IU)	Octapharma Ag	NO

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
Octanate		04-2452 (1000 IU)	Octapharma Ag	NO
Octanate		99-5085 (250 IU)	Octapharma Ag	NO
Octanate	SE/H/1070/001-002	1196/07020046	Octapharma Benelux S.A./N.V.	LU
Octanate	SE/H/1070/001-002	1196/07020047	Octapharma Benelux S.A./N.V.	LU
Octanate	SE/H/1070/001-004	BE282676	Octapharma Benelux S.A./N.V.	BE
Octanate	SE/H/1070/001-004	BE282685	Octapharma Benelux S.A./N.V.	BE
Octanate	SE/H/1070/001-004	BE350953	Octapharma Benelux S.A./N.V.	BE
Octanate	SE/H/1070/001-004	BE467742	Octapharma Benelux S.A./N.V.	BE
Octanate	SE/H/1070/001-004	BE467751	Octapharma Benelux S.A./N.V.	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
Octanate	SE/H/1070/001-002	3400956578511 (250 IU)	Octapharma France	FR
Octanate	SE/H/1070/001-002	3400956578689 (500 IU)	Octapharma France	FR
Octanate	SE/H/1070/001-002	3400956578740 (1000 IU)	Octapharma France	FR
Octanate		10500A/97-1	Octapharma Gmbh	DE
Octanate		10500A/97-2	Octapharma Gmbh	DE
Octanate		10500A/97-3	Octapharma Gmbh	DE
Octanate	SE/H/1070/001-002	RVG 29925	Octapharma Gmbh	NL
Octanate	SE/H/1070/001-002	RVG 29926	Octapharma Gmbh	NL
Octanate	SE/H/1070/001-002	55402	Octapharma Hellas A.E.	GR

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
Octanate	SE/H/1070/001-002	55403	Octapharma Hellas A.E.	GR
Octanate	SE/H/1070/001-002	55404	Octapharma Hellas A.E.	GR
Octanate	SE/H/1070/01-04	040112017/M	Octapharma Italy	IT
Octanate	SE/H/1070/01-04	040112029/M	Octapharma Italy	IT
Octanate	SE/H/1070/01-04	040112031/M	Octapharma Italy	IT
Octanate	SE/H/1070/01-04	40112056	Octapharma Italy	IT
Octanate	SE/H/1070/01-04	40112068	Octapharma Italy	IT
Octanate		16/0016/00-S (250 IU)	Octapharma Pharmazeutika Produktionsgesmbh	SK
Octanate		16/0017/00-S (500 IU)	Octapharma Pharmazeutika Produktionsgesmbh	SK

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
Octanate		16/0018/00-S (1000 IU)	Octapharma Pharmazeutika Produktionsgesmbh	SK
Octanate	SE/H/1070/001-002	2-00251	Octapharma Pharmazeutika Produktionsgesmbh	AT
Octanate	SE/H/1070/001-002	2-00252	Octapharma Pharmazeutika Produktionsgesmbh	AT
Octanate	SE/H/1070/001-002	5315809 (500 IU)	Octapharma Produtos Farmaceuticos, Lda.	PT
Octanate	SE/H/1070/001-002	5315817 (250 IU)	Octapharma Produtos Farmaceuticos, Lda.	PT
Octanate	SE/H/1070/01-02	5315825	Octapharma Produtos Farmaceuticos, Lda.	PT
Octanate	SE/H/1070/001-002	66917	Octapharma S.A.	ES
Octanate	SE/H/1070/001-002	66916	Octapharma S.A.	ES
Octanate	SE/H/1070/001	PL 10673/0018	Octapharma-Ltd	GB

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
Octanate	SE/H/1070/001-002	PA 521/12/1 (250 IU)	Octapharma-Ltd	IE
Octanate	SE/H/1070/001-002	PA 521/12/2 (500 IU)	Octapharma-Ltd	IE
Octanate	SE/H/1070/001-002	PA 521/12/3 (1000 IU)	Octapharma-Ltd	IE
Octanate	SE/H/1070/002	PL 10673/0019	Octapharma-Ltd	GB
Octanate	SE/H/1070/003-004	PA0521/012/004	Octapharma-Ltd	IE
Octanate	SE/H/1070/003-004	PA0521/012/005	Octapharma-Ltd	IE
Octanate Lv	SE/H/1070/003-004	MA754/00403	Octapharma (Ip)-Ltd.	MT
Octanate Lv	SE/H/1070/003-004	MA754/00404	Octapharma (Ip)-Ltd.	MT
Octanate LV	SE/H/1070/03-04	22264	Octapharma (Ip)-Ltd.	PL

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
Octanate LV	SE/H/1070/03-04	22265	Octapharma (Ip)-Ltd.	PL
Octanate Lv	SE/H/1070/003	53723	Octapharma Ab	DK
Octanate Lv	SE/H/1070/003-004	50693	Octapharma Ab	SE
Octanate Lv	SE/H/1070/003-004	50694	Octapharma Ab	SE
Octanate Lv	SE/H/1070/004	53779	Octapharma Ab	DK
Octanate LV	SE/H/1070/03-04	RVG 114882	Octapharma GmbH	NL
Octanate LV	SE/H/1070/03-04	RVG 117887	Octapharma GmbH	NL
Octanate Lv	SE/H/1070/003	235961	Octapharma Pharmazeutika Produktionsgesmbh	AT
Octanate Lv	SE/H/1070/004	235962	Octapharma Pharmazeutika Produktionsgesmbh	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
Octanate Lv	SE/H/1070/003-004	PL 10673/0039 (500 IU/5 ML)	Octapharma-Ltd	GB
Octanate Lv	SE/H/1070/003-004	PL 10673/0040 (1000 IU/5 ML)	Octapharma-Ltd	GB
Optivate		PL08801/0051	Bio Products Laboratory	GB
Optivate		PL08801/0055	Bio Products Laboratory	GB
Optivate		PEI.H.11611.03.1	Bio Products Laboratory	DE
Optivate		PEI.H.11611.01.1	Bio Products Laboratory	DE
Optivate		PEI.H.11611.02.1	Bio Products Laboratory	DE
Optivate		5488176	Bio Products Laboratory	PT
Optivate		5488200	Bio Products Laboratory	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
Optivate		5488218	Bio Products Laboratory	PT
ХЕМОКТИН	DE/H/0478/001	20100480	Biotest Pharma Gmbh	BG
ХЕМОКТИН	DE/H/0478/002	20100478	Biotest Pharma Gmbh	BG
ХЕМОКТИН	DE/H/0478/003	20100479	Biotest Pharma Gmbh	BG