



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2020
EMA/348432/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00001620/201911



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
Amofil 1000 IU injektiokuiva-aine ja liuotin, liuosta varten	not available	10424	SANQUIN PLASMA PRODUCTS B.V.	FI
Amofil 1000 IU pulver och vätska till injektionsvätska, lösning Koagulationsfaktor VIII, human	not available	10424	SANQUIN PLASMA PRODUCTS B.V.	FI
Amofil 500 IU injektiokuiva-aine ja liuotin, liuosta varten	not available	10424	SANQUIN PLASMA PRODUCTS B.V.	FI
Amofil 500 IU pulver och vätska till injektionsvätska, lösning Koagulationsfaktor VIII, human	not available	10424	SANQUIN PLASMA PRODUCTS B.V.	FI
Beriate ® 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/0483/003	2-00213	CSL BEHRING GMBH	AT
Beriate ® 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/0483/001	2-00213	CSL BEHRING GMBH	AT
Beriate ® 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/0483/002	2-00213	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 ® 200 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/0483/004	2-00403	CSL BEHRING GMBH	AT
Beriate 1.000 U. I. polvo y disolvente para solución inyectable o perfusión	DE/H/0483/003	63.009	CSL BEHRING GMBH	ES
Beriate 100 NE/ml por és oldószer oldatos injekcióhoz vagy infúzióhoz	DE/H/0483/001	OGYI-T-4357/03	CSL BEHRING GMBH	HU
Beriate 100 NE/ml por és oldószer oldatos injekcióhoz vagy infúzióhoz	DE/H/0483/002	OGYI-T-4357/01	CSL BEHRING GMBH	HU
Beriate 100 NE/ml por és oldószer oldatos injekcióhoz vagy infúzióhoz	DE/H/0483/003	OGYI-T-4357/02	CSL BEHRING GMBH	HU
Beriate 1000 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje	DE/H/0483/003	H/15/01957/003	CSL BEHRING GMBH	SI
Beriate 1000 IU Prášek a rozpouštědlo pro injekční nebo infuzní roztok	DE/H/0483/003	75/205/15-C	CSL BEHRING GMBH	CZ
Beriate 1000 IU prášok a rozpúšťadlo na	DE/H/0483/003	16/0148/15-S	CSL BEHRING GMBH	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
injekčný/infúzny roztok				
Beriate 1000 U.I./10 ml, pó e solvente para solução injetável ou para perfusão	DE/H/0483/003	2630887	CSL BEHRING GMBH	PT
Beriate 1000 UI pulbere si solvent pentru solutie injectabila sau perfuzabila	DE/H/0483/003	7559/2015/01	CSL BEHRING GMBH	RO
Beriate 2.000 U. I. polvo y disolvente para solución inyectable o perfusión	DE/H/0483/004	76960	CSL BEHRING GMBH	ES
Beriate 200 NE/ml por és oldószer oldatos injekcióhoz vagy infúzióhoz	DE/H/0483/004	OGYI-T-4357/04	CSL BEHRING GMBH	HU
Beriate 2000 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje	DE/H/0483/004	H/15/01957/004	CSL BEHRING GMBH	SI
Beriate 2000 IU Prášek a rozpouštědlo pro injekční nebo infuzní roztok	DE/H/0483/004	75/206/15-C	CSL BEHRING GMBH	CZ
Beriate 2000 IU prášok a rozpúšťadlo na injekčný/infúzny roztok	DE/H/0483/004	16/0149/15-S	CSL BEHRING GMBH	SK
Beriate 2000 U.I./10 ml, pó e solvente para solução injetável	DE/H/0483/004	5659503	CSL BEHRING GMBH	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
ou para perfusão				
Beriate 2000 UI pulbere si solvent pentru solutie injectabila sau perfuzabila	DE/H/0483/004	7560/2015/01	CSL BEHRING GMBH	RO
Beriate 2000 UI, Polvere e solvente per soluzione per iniezione o infusione	DE/H/0483/004	033657040	CSL BEHRING GMBH	IT
Beriate 250 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje	DE/H/0483/001	H/15/01957/001	CSL BEHRING GMBH	SI
Beriate 250 IU prášok a rozpúšťadlo na injekčný/infúzny roztok	DE/H/0483/001	16/0146/15-S	CSL BEHRING GMBH	SK
Beriate 250 U.I./2,5 ml, pó e solvente para solução injetável ou para perfusão	DE/H/0483/001	2630689	CSL BEHRING GMBH	PT
Beriate 250 UI pulbere si solvent pentru solutie injectabila sau perfuzabila	DE/H/0483/001	7557/2015/01	CSL BEHRING GMBH	RO
Beriate 250 UI, Polvere e solvente per soluzione per iniezione o infusione	DE/H/0483/001	033657014	CSL BEHRING GMBH	IT
Beriate 500 i.e. prašek in vehikel za raztopino za	DE/H/0483/002	H/15/01957/002	CSL BEHRING GMBH	SI

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
injiciranje/infundiranje				
Beriate 500 IU prášok a rozpúšťadlo na injekčný/infúzny roztok	DE/H/0483/002	16/0147/15-S	CSL BEHRING GMBH	SK
Beriate 500 U. I. polvo y disolvente para solución inyectable o perfusión	DE/H/0483/002	63.023	CSL BEHRING GMBH	ES
Beriate 500 U.I./5 ml, pó e solvente para solução injetável ou para perfusão	DE/H/0483/002	2630788	CSL BEHRING GMBH	PT
Beriate 500 UI pulbere si solvent pentru solutie injectabila sau perfuzabila	DE/H/0483/002	7558/2015/01	CSL BEHRING GMBH	RO
Beriate 500 UI, Polvere e solvente per soluzione per iniezione o infusione	DE/H/0483/002	033657026	CSL BEHRING GMBH	IT
Beriate prašak i otapalo za otopinu za injekciju ili infuziju	DE/H/0483/001	HR-H-757879572	CSL BEHRING GMBH	HR
Beriate prašak i otapalo za otopinu za injekciju ili infuziju	DE/H/0483/002	HR-H-027274549	CSL BEHRING GMBH	HR
Beriate prašak i otapalo za otopinu za injekciju ili infuziju	DE/H/0483/003	HR-H-489227633	CSL BEHRING GMBH	HR
Beriate prašak i otapalo za	DE/H/0483/004	HR-H-856167715	CSL BEHRING GMBH	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
otopinu za injekciju ili infuziju				
Beriate, polvere e solvente per soluzione iniettabile o per infusione	DE/H/0483/003	033657038	CSL BEHRING GMBH	IT
Beriate, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan / do infuzji	DE/H/0483/003	22398	CSL BEHRING GMBH	PL
Beriate, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan / do infuzji	DE/H/0483/001	22396	CSL BEHRING GMBH	PL
Beriate, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan / do infuzji	DE/H/0483/002	22397	CSL BEHRING GMBH	PL
Beriate, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan / do infuzji	DE/H/0483/004	22 399	CSL BEHRING GMBH	PL
Beriate® 1000 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	DE/H/0483/003	10505A/98-3	CSL BEHRING GMBH	DE

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Beriate® 2000 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	DE/H/0483/004	10505A/98-4	CSL BEHRING GMBH	DE
Beriate® 250 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	DE/H/0483/001	10505A/98-1	CSL BEHRING GMBH	DE
Beriate® 500 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	DE/H/0483/002	10505A/98-2	CSL BEHRING GMBH	DE
EMOCLOT 1000 UI/10 ml Polvere e solvente per soluzione per infusione	not available	023564228	KEDRION S.P.A.	IT
EMOCLOT 500 IU powder and solvent for solution for infusion	not available	20040435	KEDRION S.P.A.	BG
EMOCLOT 500 UI/10 ml Polvere e solvente per soluzione per infusione	not available	023564216	KEDRION S.P.A.	IT
EMOCLOT D.I. 1000, pó e solvente para solução injectável	not available	3071180	KEDRION S.P.A.	PT
EMOCLOT D.I. 500, pó e	not available	2908986	KEDRION S.P.A.	PT

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solvente para solução injectável				
EMOCLOT, 1000 j.m., proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji	not available	9894	KEDRION S.P.A.	PL
EMOCLOT, 500 j.m., proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań i infuzji	not available	9893	KEDRION S.P.A.	PL
FACTANE 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 562 116 1 6	LFB BIOMEDICAMENTS	FR
FACTANE 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 562 115 5 5	LFB BIOMEDICAMENTS	FR
FACTANE 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 562 117 8 4	LFB BIOMEDICAMENTS	FR
FACTANE 100 UI/ml, poudre et solvant pour solution injectable	not available	2006018366	LFB BIOMEDICAMENTS	LU
FACTANE 100 UI/ml, poudre et solvant pour solution injectable	not available	2006018367	LFB BIOMEDICAMENTS	LU
Factane 200 UI/mL, poudre et solvant pour solution injectable	not available	34009 585 201 5 0	LFB BIOMEDICAMENTS	FR
Factane 200 UI/mL, poudre et	not available	34009 585 200 9 9	LFB BIOMEDICAMENTS	FR

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solvant pour solution injectable				
Factor VIII 100 UI/ml Octapharma Polvo y disolvente para solución inyectable	not available	83774	OCTAPHARMA S.A.	ES
Factor VIII 200 UI/ml Octapharma Polvo y disolvente para solución inyectable	not available	83775	OCTAPHARMA S.A.	ES
Faktor VIII SDH Intersero 1000 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	16844.02.00	INTERSERO GMBH	DE
Faktor VIII SDH Intersero 250 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	16844.00.00	INTERSERO GMBH	DE
Faktor VIII SDH Intersero 500 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	16844.01.00	INTERSERO GMBH	DE
Haemoclin 1000 NE por és oldószer oldatos injekcióhoz	DE/H/0478/003	OGYI-T-2110/03	BIOTEST PHARMA GMBH	HU
Haemoclin 1000 Pó e solvente para solução injetável	DE/H/0478/003	5295027	BIOTEST PHARMA GMBH	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
Haemoctin 1000 Polvo y disolvente para solución inyectable	DE/H/0478/003	70009	BIOTEST PHARMA GMBH	ES
Haemoctin 1000 Powder and solvent for solution for injection	DE/H/0478/003	PL 04500/0010	BIOTEST PHARMA GMBH	UK
Haemoctin 1000 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	DE/H/0478/003	17880	BIOTEST PHARMA GMBH	PL
Haemoctin 1000 U.I. Polvere e solvente per soluzione iniettabile	DE/H/0478/003	038541037	BIOTEST PHARMA GMBH	IT
Haemoctin 250 NE por és oldószer oldatos injekcióhoz	DE/H/0478/001	OGYI-T-2110/02	BIOTEST PHARMA GMBH	HU
Haemoctin 250 Pó e solvente para solução injetável	DE/H/0478/001	5295001	BIOTEST PHARMA GMBH	PT
Haemoctin 250 Powder and solvent for solution for injection	DE/H/0478/001	PL 04500/0009	BIOTEST PHARMA GMBH	UK
Haemoctin 250 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	DE/H/0478/001	17878	BIOTEST PHARMA GMBH	PL
Haemoctin 250 U.I. Polvere e solvente per soluzione	DE/H/0478/001	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
iniettabile				
Haemoctin 500 NE por és oldószer oldatos injekcióhoz	DE/H/0478/002	OGYI-T-2110/01	BIOTEST PHARMA GMBH	HU
Haemoctin 500 Pó e solvente para solução injetável	DE/H/0478/002	5295019	BIOTEST PHARMA GMBH	PT
Haemoctin 500 Polvo y disolvente para solución inyectable	DE/H/0478/002	70008	BIOTEST PHARMA GMBH	ES
Haemoctin 500 Powder and solvent for solution for injection	DE/H/0478/002	PL 04500/0009	BIOTEST PHARMA GMBH	UK
Haemoctin 500 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	DE/H/0478/002	17879	BIOTEST PHARMA GMBH	PL
Haemoctin 500 U.I. Polvere e solvente per soluzione iniettabile	DE/H/0478/002	038541025	BIOTEST PHARMA GMBH	IT
Haemoctin SDH 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0478/003	2-00376	BIOTEST AUSTRIA GMBH	AT
Haemoctin SDH 1000 Powder and solvent for solution for	DE/H/0478/003	MA008/00103	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
injection				
Haemoctin SDH 1000 prášek a rozpouštědlo pro injekční roztok	DE/H/0478/003	75/139/92-C/C	BIOTEST PHARMA GMBH	CZ
Haemoctin SDH 1000 Pulbere și solvent pentru soluție injectabilă	DE/H/0478/003	6201/2014/01	BIOTEST PHARMA GMBH	RO
Haemoctin SDH 1000 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0478/003	16841.02.00	BIOTEST PHARMA GMBH	DE
Haemoctin SDH 1000 TV milteliai ir tirpiklis injekciniam tirpalui	not available	LT/1/96/1260/003	BIOTEST PHARMA GMBH	LT
Haemoctin SDH 250 Powder and solvent for solution for injection	DE/H/0478/001	MA008/00101	BIOTEST PHARMA GMBH	MT
Haemoctin SDH 250 prášek a rozpouštědlo pro injekční roztok	DE/H/0478/001	75/139/92-A/C	BIOTEST PHARMA GMBH	CZ
Haemoctin SDH 250 Pulbere și solvent pentru soluție injectabilă	DE/H/0478/001	6199/2014/01	BIOTEST PHARMA 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
Haemoctin SDH 250 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0478/001	16841.00.00	BIOTEST PHARMA GMBH	DE
Haemoctin SDH 250 TV milteliai ir tirpiklis injekciniam tirpalui	not available	LT/1/96/1260/001	BIOTEST PHARMA GMBH	LT
Haemoctin SDH 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0478/001	2-00375	BIOTEST AUSTRIA GMBH	AT
Haemoctin SDH 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0478/002	2-00375	BIOTEST AUSTRIA GMBH	AT
Haemoctin SDH 500 Powder and solvent for solution for injection	DE/H/0478/002	MA008/00102	BIOTEST PHARMA GMBH	MT
Haemoctin SDH 500 prášek a rozpouštědlo pro injekční roztok	DE/H/0478/002	75/139/92-B/C	BIOTEST PHARMA GMBH	CZ
Haemoctin SDH 500 Pulbere și solvent pentru soluție injectabilă	DE/H/0478/002	6200/2014/01	BIOTEST PHARMA GMBH	RO
Haemoctin SDH 500 Pulver und	DE/H/0478/002	16841.01.00	BIOTEST PHARMA 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
Lösungsmittel zur Herstellung einer Injektionslösung				
Haemoctin SDH 500 TV milteliai ir tirpiklis injekciniam tirpalui	not available	LT/1/96/1260/002	BIOTEST PHARMA GMBH	LT
Humaclo 1000 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-22285/02	HUMAN BIOPLAZMA MANUFACTURING AND TRADING LLC	HU
Humaclo 500 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-22285/01	HUMAN BIOPLAZMA MANUFACTURING AND TRADING LLC	HU
KLOTT 1000 UI/10 ml Polvere e solvente per soluzione per infusione	not available	041649029	KEDRION S.P.A.	IT
KLOTT 500 UI/10 ml Polvere e solvente per soluzione per infusione	not available	041649017	KEDRION S.P.A.	IT
Octafil Low 100 IU/mL Injektiokuiva-aine ja liuotin	SE/H/1070/003	32045	OCTAPHARMA AB	FI
Octafil Low 200 I.E./mL Injektiokuiva-aine ja liuotin	SE/H/1070/004	32046	OCTAPHARMA AB	FI
OCTANATE 250 IU, prášok a rozpúšťadlo na injekčný roztok	not available	16/0016/00-S	OCTAPHARMA PHARMAZEUTIKA	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
			PRODUKTIONSGESMBH	
OCTANATE 500 IU, prášok a rozpúšťadlo na injekčný roztok ľudský koagulačný faktor VIII	not available	16/0017/00-S	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	SK
Octanate 1000 UI/5 ml, pó e solvente para solução injetável	SE/H/1070/004	5639505	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Octanate 250 UI/5 ml, pó e solvente para solução injetável	SE/H/1070/001	5315817	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Octanate 500 UI/5 ml, pó e solvente para solução injetável	SE/H/1070/003	5639513	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Octanate LV 200 UI/mL pulbere și solvent pentru soluție injectabilă	SE/H/1070/004	7187/2014/01	OCTAPHARMA (IP) SPRL	RO
Octanate 100 i.e./ml prašek in vehikel za raztopino za injiciranje	SE/H/1070/002	H/11/01143/001	OCTAPHARMA (IP) SPRL	SI
Octanate 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	SE/H/1070/002	2-00252	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanate 100 IE/mL poeder en oplosmiddel voor oplossing voor injectie	SE/H/1070/002	BE282676	OCTAPHARMA BENELUX S.A.	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 100 IU/mL poudre et solvant pour solution injectable	SE/H/1070/003	BE467742	OCTAPHARMA BENELUX S.A.	BE
Octanate 100 IU/ml Poudre et solvant pour solution injectable	SE/H/1070/002	2011010966 - NN 0450097	OCTAPHARMA BENELUX S.A.	LU
Octanate 100 IU/ml Powder and solvent for solution for injection	SE/H/1070/002	MA1219/00702	OCTAPHARMA (IP) SPRL	MT
Octanate 100 IU/mL powder and solvent for solution for injection	SE/H/1070/002	PL10673/0019	OCTAPHARMA-LTD	UK
Octanate 100 IU/ml Prášek a rozpouštědlo pro injekční roztok	SE/H/1070/002	75/004/00-C	OCTAPHARMA (IP) SPRL	CZ
Octanate 100 TV/mL milteliai ir tirpiklis injekciniam tirpalui	SE/H/1070/003	LT/1/05/0261/004	OCTAPHARMA (IP) SPRL	LT
Octanate 100 TV/ml milteliai ir tirpiklis injekciniam tirpalui	SE/H/1070/002	LT/1/05/0261/003	OCTAPHARMA (IP) SPRL	LT
Octanate 100 UI/ml Polvere e solvente per soluzione iniettabile	SE/H/1070/003	040112056	OCTAPHARMA ITALY S.P.A.	IT
Octanate 100 UI/ml Polvere e solvente per soluzione iniettabile	SE/H/1070/002	040112031/M	OCTAPHARMA ITALY S.P.A.	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
Octanate 100 UI/ml pulbere și solvent pentru soluție injectabilă	SE/H/1070/002	8849/2016/01	OCTAPHARMA (IP) SPRL	RO
OCTANATE 100 UI/ml, poudre et solvant pour solution injectable	SE/H/1070/002	3400956578740	OCTAPHARMA FRANCE	FR
Octanate 1000 (100 IU/ml) Κόνις και διαλύτης για ενέσιμο διάλυμα	SE/H/1070/002	20062	OCTAPHARMA (IP) SPRL	CY
OCTANATE 1000 IE pulver og væske til injeksjonsvæske, oppløsning	not available	04-2452	OCTAPHARMA AS	NO
Octanate 1000 IU powder and solvent for solution for injection	SE/H/1070/004	PA2219/004/003	OCTAPHARMA (IP) SPRL	IE
OCTANATE 1000 IU prašak i otapalo za otopinu za injekciju	not available	HR-H-748572974	JANA PHARM D.O.O.	HR
OCTANATE 1000 IU, prášok a rozpúšťadlo na injekčný roztok	not available	16/0018/00-S	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	SK
Octanate 1000 IU/5 ml prášek a rozpouštědlo pro injekční roztok	SE/H/1070/004	75/140/15-C	OCTAPHARMA (IP) SPRL	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
Octanate 1000 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-6840/01	OCTAPHARMA (IP) SPRL	HU
OCTANATE 1000 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	10500A/97-3	OCTAPHARMA GMBH	DE
Octanate 1000 SV pulveris un škidinatajs injekciju škiduma pagatavošanai	SE/H/1070/002	05-0049	OCTAPHARMA (IP) SPRL	LV
Octanate 1000 SV/5 ml pulveris un škidinatajs injekciju škiduma pagatavošanai	SE/H/1070/004	15-0022	OCTAPHARMA (IP) SPRL	LV
Octanate 1000 UI/10 mL, pó e solvente para solução injetável	SE/H/1070/002	5315825	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
OCTANATE 1000, 1000 RÜ süstelahuse pulber ja lahusti	not available	398802	OCTAPHARMA AB	EE
Octanate 1000, poeder en oplosmiddel voor oplossing voor injectie 100 IE/ml	SE/H/1070/002	RVG 29926	OCTAPHARMA GMBH	NL
Octanate 200 IU/mL poudre et solvant pour solution injectable	SE/H/1070/004	BE467751	OCTAPHARMA BENELUX S.A.	BE
Octanate 200 IU/ml Poudre et solvant pour solution injectable	SE/H/1070/004	2015120224 - NN 0798831	OCTAPHARMA BENELUX S.A.	LU
Octanate 200 TV/mL milteliai ir	SE/H/1070/004	LT/1/05/0261/005	OCTAPHARMA (IP) SPRL	LT

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
tirpiklis injekciniam tirpalui				
Octanate 200 UI/ml Polvere e solvente per soluzione iniettabile	SE/H/1070/004	040112068	OCTAPHARMA ITALY S.P.A.	IT
OCTANATE 250 IE pulver og væske til injeksjonsvæske, opløsning	not available	99-5085	OCTAPHARMA AS	NO
OCTANATE 250 IU prašak i otapalo za otopinu za injekciju	not available	HR-H-515618349	JANA PHARM D.O.O.	HR
Octanate 250 IU. powder and solvent for solution for injection	SE/H/1070/001	PA2219/004/001	OCTAPHARMA (IP) SPRL	IE
Octanate 250 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-6840/02	OCTAPHARMA (IP) SPRL	HU
OCTANATE 250 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	10500A/97-1	OCTAPHARMA GMBH	DE
Octanate 250 SV pulveris un škidinatajs injekciju škiduma pagatavošanai	SE/H/1070/001	05-0047	OCTAPHARMA (IP) SPRL	LV
Octanate 250, poeder en oplosmiddel voor oplossing voor injectie 50 IE/ml	SE/H/1070/001	RVG 29925	OCTAPHARMA GMBH	NL

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 250/500 (50 IU/ml) Κόνις και διαλύτης για ενέσιμο διάλυμα	SE/H/1070/001	20061	OCTAPHARMA (IP) SPRL	CY
Octanate 250/500 (50 IU/ml) Κόνις και διαλύτης για ενέσιμο διάλυμα	SE/H/1070/001	20061	OCTAPHARMA (IP) SPRL	CY
Octanate 50 i.e./ml prašek in vehikel za raztopino za injiciranje	SE/H/1070/001	H/11/01143/002	OCTAPHARMA (IP) SPRL	SI
Octanate 50 i.e./ml prašek in vehikel za raztopino za injiciranje	SE/H/1070/001	H/11/01143/003	OCTAPHARMA (IP) SPRL	SI
Octanate 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	SE/H/1070/001	2-00251	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanate 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	SE/H/1070/001	2-00251	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanate 50 IU/ml poudre et solvant pour solution injectable	SE/H/1070/001	BE282685	OCTAPHARMA BENELUX S.A.	BE
Octanate 50 IU/ml poudre et solvant pour solution injectable	SE/H/1070/001	BE350953	OCTAPHARMA BENELUX S.A.	BE
Octanate 50 IU/ml poudre et	SE/H/1070/001	2011010965 - NN	OCTAPHARMA BENELUX	LU

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
solvant pour solution injectable		0450083	S.A.	
Octanate 50 IU/ml poudre et solvant pour solution injectable	SE/H/1070/001	2011010965 - NN 0477347	OCTAPHARMA BENELUX S.A.	LU
Octanate 50 IU/ml Powder and solvent for solution for injection	SE/H/1070/001	MA1219/00701	OCTAPHARMA (IP) SPRL	MT
Octanate 50 IU/ml Powder and solvent for solution for injection	SE/H/1070/001	MA1219/00705	OCTAPHARMA (IP) SPRL	MT
Octanate 50 IU/mL powder and solvent for solution for injection	SE/H/1070/001	PL10673/0018	OCTAPHARMA-LTD	UK
Octanate 50 IU/mL powder and solvent for solution for injection	SE/H/1070/001	PL10673/0018	OCTAPHARMA-LTD	UK
Octanate 50 IU/ml prášek a rozpouštědlo pro injekční roztok	SE/H/1070/001	75/410/91-B/C	OCTAPHARMA (IP) SPRL	CZ
Octanate 50 IU/ml prášek a rozpouštědlo pro injekční roztok	SE/H/1070/001	75/410/91-B/C	OCTAPHARMA (IP) SPRL	CZ
Octanate 50 TV/ml milteliai ir tirpiklis injekciniam tirpalui	SE/H/1070/001	LT/1/05/0261/001	OCTAPHARMA (IP) SPRL	LT

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 50 TV/ml miltelīai ir tīrpiklis injekcijām tirpalui	SE/H/1070/001	LT/1/05/0261/002	OCTAPHARMA (IP) SPRL	LT
Octanate 50 UI/ml pulbere și solvent pentru soluție injectabilă	SE/H/1070/001	8848/2016/02	OCTAPHARMA (IP) SPRL	RO
Octanate 50 UI/ml pulbere și solvent pentru soluție injectabilă	SE/H/1070/001	8848/2016/01	OCTAPHARMA (IP) SPRL	RO
Octanate 50 UI/ml, Polvere e solvante per soluzione iniettabile	SE/H/1070/001	040112017/M	OCTAPHARMA ITALY S.P.A.	IT
Octanate 50 UI/ml, Polvere e solvante per soluzione iniettabile	SE/H/1070/001	040112029/M	OCTAPHARMA ITALY S.P.A.	IT
OCTANATE 50 UI/ml, poudre et solvant pour solution injectable	SE/H/1070/001	3400956578511	OCTAPHARMA FRANCE	FR
OCTANATE 50 UI/ml, poudre et solvant pour solution injectable	SE/H/1070/001	3400956578689	OCTAPHARMA FRANCE	FR
OCTANATE 500 IE pulver og væske til injeksjonsvæske, oppløsning	not available	04-2451	OCTAPHARMA AS	NO
Octanate 500 IU powder and solvent for solution for	SE/H/1070/003	PA2219/004/002	OCTAPHARMA (IP) SPRL	IE

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
injection				
OCTANATE 500 IU prašek i otapalo za otopinu za injekciju	not available	HR-H-067222873	JANA PHARM D.O.O.	HR
Octanate 500 IU/5 mL Poudre et solvant pour solution injectable	SE/H/1070/003	2015120223 - NN 0798827	OCTAPHARMA BENELUX S.A.	LU
Octanate 500 IU/5 ml prášek a rozpouštědlo pro injekční roztok	SE/H/1070/003	75/139/15-C	OCTAPHARMA (IP) SPRL	CZ
Octanate 500 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-6840/03	OCTAPHARMA (IP) SPRL	HU
OCTANATE 500 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	10500A/97-2	OCTAPHARMA GMBH	DE
Octanate 500 SV pulveris un škidinatajs injekciju škiduma pagatavošanai	SE/H/1070/001	05-0048	OCTAPHARMA (IP) SPRL	LV
Octanate 500 SV/5 ml pulveris un škidinatajs injekciju škiduma pagatavošanai	SE/H/1070/003	15-0021	OCTAPHARMA (IP) SPRL	LV
Octanate 500 UI/10 ml, pó e solvente para solução injetável	SE/H/1070/001	5315809	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
OCTANATE 500, 500 RÜ	not available	398702	OCTAPHARMA AB	EE

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
süstelahuse pulber ja lahusti				
Octanate 500, poeder en oplosmiddel voor oplossing voor injectie 50 IE/ml	SE/H/1070/001	RVG 29925	OCTAPHARMA GMBH	NL
Octanate Kons 100 i.e./ml prašek in vehikel za raztopino za injiciranje	SE/H/1070/003	H/11/01143/004	OCTAPHARMA (IP) SPRL	SI
Octanate Kons 200 i.e./ml prašek in vehikel za raztopino za injiciranje	SE/H/1070/004	H/11/01143/005	OCTAPHARMA (IP) SPRL	SI
Octanate LV 200 IU/mL powder and solvent for solution for injection	SE/H/1070/004	PL 10673/0040	OCTAPHARMA-LTD	UK
Octanate LV 100 I.E./mL Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	SE/H/1070/003	235961	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanate LV 100 IE/mL poeder en oplosmiddel voor oplossing voor injectie	SE/H/1070/003	RVG 114882	OCTAPHARMA GMBH	NL
Octanate LV 100 IE/ml pulver och vätska till injektionsvätska, lösning	SE/H/1070/003	50693	OCTAPHARMA AB	SE

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 100 IU/ml Powder and solvent for solution for injection	SE/H/1070/003	MA1219/00703	OCTAPHARMA (IP) SPRL	MT
Octanate LV 100 IU/mL powder and solvent for solution for injection	SE/H/1070/003	PL 10673/0039	OCTAPHARMA-LTD	UK
Octanate LV 100 UI/ml Polvo y disolvente para solución inyectable	SE/H/1070/003	79616	OCTAPHARMA S.A.	ES
Octanate LV 100 UI/mL pulbere și solvent pentru soluție injectabilă	SE/H/1070/003	7186/2014/01	OCTAPHARMA (IP) SPRL	RO
OCTANATE LV 100 UI/ml, poudre et solvant pour solution injectable	SE/H/1070/003	34009 550 063 9 8	OCTAPHARMA FRANCE	FR
Octanate LV 200 I.E./mL Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	SE/H/1070/004	235962	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanate LV 200 IE/mL poeder en oplosmiddel voor oplossing voor injectie	SE/H/1070/004	RVG 114887	OCTAPHARMA GMBH	NL
Octanate LV 200 IE/ml pulver och vätska till injektionsvätska,	SE/H/1070/004	50694	OCTAPHARMA AB	SE

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
lösning				
Octanate LV 200 IU/ml Powder and solvent for solution for injection	SE/H/1070/004	MA1219/00704	OCTAPHARMA (IP) SPRL	MT
Octanate LV 200 UI/ml Polvo y disolvente para solución inyectable	SE/H/1070/004	79617	OCTAPHARMA S.A.	ES
OCTANATE LV 200 UI/ml, poudre et solvant pour solution injectable	SE/H/1070/004	34009 550 065 1 0	OCTAPHARMA FRANCE	FR
Octanate LV, 100 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	SE/H/1070/003	22264	OCTAPHARMA (IP) SPRL	PL
Octanate LV, 200 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	SE/H/1070/004	22265	OCTAPHARMA (IP) SPRL	PL
Octanate LV, pulver og solvens til injektionsvæske, opløsning 100 IE/ml	SE/H/1070/003	53723	OCTAPHARMA AB	DK
Octanate LV, pulver og solvens til injektionsvæske, opløsning 200 IE/ml	SE/H/1070/004	53779	OCTAPHARMA AB	DK

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 pulver och vätska till injektionsvätska, lösning 100 IE/ml	SE/H/1070/002	21465	OCTAPHARMA AB	SE
Octanate pulver och vätska till injektionsvätska, lösning, 50 IE/ml	SE/H/1070/001	21464	OCTAPHARMA AB	SE
Octanate pulver och vätska till injektionsvätska, lösning, 50 IE/ml	SE/H/1070/001	21464	OCTAPHARMA AB	SE
Octanate, 100 j.m./ml, proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan	SE/H/1070/002	17549	OCTAPHARMA (IP) SPRL	PL
Octanate, 50 j.m./ml, proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan	SE/H/1070/001	17548	OCTAPHARMA (IP) SPRL	PL
Octanate, 50 j.m./ml, proszek i rozpuszczalnik do sporzadzania roztworu do wstrzykiwan	SE/H/1070/001	17548	OCTAPHARMA (IP) SPRL	PL
Octanate, pulver og solvens til injektionsvæske, opløsning 100 IE/ml	SE/H/1070/002	35522	OCTAPHARMA AB	DK
Octanate, pulver og solvens til injektionsvæske, opløsning 50	SE/H/1070/001	35521	OCTAPHARMA AB	DK

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
IE/ml				
Octanate, pulver og solvens til injektionsvæske, opløsning 50 IE/ml	SE/H/1070/001	35521	OCTAPHARMA AB	DK
Optivate (human factor VIII) 100 IU/mL, a powder for solution for injection.	not available	PL08801/0055	BIO PRODUCTS LABORATORY	UK
Optivate 1000 UI Pó e solvente para solução injectável, Factor VIII de coagulação humana	UK/H/4591/001	5488218	BIO PRODUCTS LABORATORY	PT
Optivate 1000 UI pulbere și solvent pentru soluție injectabilă Factor VIII de coagulare uman	UK/H/4591/001	8069/2015/03	BIO PRODUCTS LABORATORY	RO
Optivate 250 IU Pó e solvente para solução injectável, Factor VIII de coagulação humana	UK/H/4591/001	5488176	BIO PRODUCTS LABORATORY	PT
Optivate 250 UI pulbere si solvent pentru solutie injectabila Factor VIII de coagulare uman	UK/H/4591/001	8069/2015/01	BIO PRODUCTS LABORATORY	RO
Optivate 500 IU Pó e solvente para solução injectável, Factor VIII de coagulação humana	UK/H/4591/001	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 500 UI pulbere și solvent pentru soluție injectabilă Factor VIII de coagulare uman	UK/H/4591/001	8069/2015/02	BIO PRODUCTS LABORATORY	RO
Optivate® 250 IU powder and solvent for solution for injection Human coagulation factor VIII	UK/H/4591/001	MA049/00901	BIO PRODUCTS LABORATORY	MT
Optivate® 250 IU prášok a rozpúšťadlo na injekčný roztok Ludský koagulačný faktor VIII	UK/H/4591/001	16/0365/15-S	BIO PRODUCTS LABORATORY	SK
Optivate® 250 IU, 500 IU, 1000 IU, powder and solvent for solution for injection Human coagulation factor VIII.	UK/H/4591/001	PL 08801/0051	BIO PRODUCTS LABORATORY	UK
Optivate® 250 IU, 500 IU, 1000 IU, powder and solvent for solution for injection. Human coagulation factor VIII.	UK/H/4591/01/E/01	MR/DRL/0013-0015/2015	BIO PRODUCTS LABORATORY	PL
Optivate® 250 IU, 500 IU, 1000 IU, κόκκους και διαλύτης για ενέσιμο διάλυμα Ανθρώπινος παράγοντας πήξης VIII	UK/H/4591/001	21627	BIO PRODUCTS LABORATORY	CY
Optivate® 500 IU prášok a rozpúšťadlo na injekčný roztok	UK/H/4591/001	16/0366/15-S	BIO PRODUCTS	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
Људскý коагулачнý фактор VIII			LABORATORY	
Pharmavate, 100 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	not available	22979	PHARMA INNOVATIONS SP. Z O.O.	PL
Pharmavate, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	not available	22978	PHARMA INNOVATIONS SP. Z O.O.	PL
Бериате 1000 IU, прах и разтворител за инжекционен или инфузионен разтвор	DE/H/0483/003	20150023	CSL BEHRING GMBH	BG
Бериате 2000 IU, прах и разтворител за инжекционен или инфузионен разтвор	DE/H/0483/004	20150024	CSL BEHRING GMBH	BG
Бериате 250 IU, прах и разтворител за инжекционен или инфузионен разтвор	DE/H/0483/001	20150021	CSL BEHRING GMBH	BG
Бериате 500 IU, прах и разтворител за инжекционен и инфузионен разтвор	DE/H/0483/002	20150022	CSL BEHRING GMBH	BG
Октанейт 1000	not available	20020775	OCTAPHARMA (IP) SPRL	BG
Октанейт 500	not available	20020774	OCTAPHARMA (IP) SPRL	BG

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
Хемотин 1000 IU прах и разтворител за инжекционен разтвор	DE/H/0478/003	20100479	BIOTEST PHARMA GMBH	BG
Хемотин 250 IU прах и разтворител за инжекционен разтвор	DE/H/0478/001	20100480	BIOTEST PHARMA GMBH	BG
Хемотин 500 IU прах и разтворител за инжекционен разтвор	DE/H/0478/002	20100478	BIOTEST PHARMA GMBH	BG