



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 March 2020
EMA/118966/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: human coagulation factor IX

Procedure no.: PSUSA/00001617/201907

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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
AIMAFIX 1000 UI/10 ml, polvere e solvente per soluzione per infusione	not available	025841103	KEDRION S.P.A.	IT
AIMAFIX 500 UI/10 ml, polvere e solvente per soluzione per infusione	not available	025841089	KEDRION S.P.A.	IT
AlphaNine 1000 UI Polvere e solvente per soluzione per infusione	not available	029250077	GRIFOLS ITALIA S.P.A	IT
AlphaNine 1500 UI Polvere e solvente per soluzione per infusione	not available	029250089	GRIFOLS ITALIA S.P.A	IT
AlphaNine 500 UI Polvere e solvente per soluzione per infusione	not available	029250065	GRIFOLS ITALIA S.P.A	IT
AlphaNine® 1000 IU, powder and solvent for solution for injection	not available	PL 12930/0013	ISTITUTO GRIFOLS, S.A.	UK
AlphaNine® 1000, poeder en oplosmiddel voor oplossing voor injectie 100 IE/ml	not available	RVG 17397	ISTITUTO GRIFOLS, S.A.	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
AlphaNine® 1000, Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung	not available	6408.01.00	GRIFOLS DEUTSCHLAND GMBH	DE
AlphaNine® 1500 IU, powder and solvent for solution for injection.	not available	PL 12930/0014	INSTITUTO GRIFOLS, S.A.	UK
AlphaNine® 500 IU, powder and solvent for solution for injection	not available	PL 12930/0012	INSTITUTO GRIFOLS, S.A.	UK
AlphaNine® 500, poeder en oplosmiddel voor oplossing voor injectie 50 IE/ml	not available	RVG 17396	INSTITUTO GRIFOLS, S.A.	NL
AlphaNine® 500, Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung	not available	6408.00.00	GRIFOLS DEUTSCHLAND GMBH	DE
Berinin P 1200 Proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań lub infuzji	not available	4839	CSL BEHRING GMBH	PL
BERININ P 1200 UI polvo y disolvente para solución para inyección o perfusión	not available	65405	CSL BEHRING GMBH	ES

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
Berinin P 600 NE por és oldószer oldatos injekcióhoz vagy infúzióhoz	not available	OGYI-T-4361/01	CSL BEHRING GMBH	HU
Berinin P 600 Proszek i rozpuszczalnik do sporządzenia roztworu do wstrzykiwań lub infuzji	not available	4838	CSL BEHRING GMBH	PL
Berinin® P 1200 Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	6121.02.00	CSL BEHRING GMBH	DE
Berinin® P 600 Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	6121.01.00	CSL BEHRING GMBH	DE
BETAFACT 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 574 418 8 3	LFB BIOMEDICAMENTS	FR
BETAFACT 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 574 419 4 4	LFB BIOMEDICAMENTS	FR

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
BETAFACT 1000 IU, PROSZEK I ROZPUSZCZALNIK DO SPORZĄDZANIA ROZTWORU DO WSTRZYKIWAŃ	FR/H/0156/001	20033	LFB BIOMEDICAMENTS	PL
BETAFACT 250 IU, PROSZEK I ROZPUSZCZALNIK DO SPORZĄDZANIA ROZTWORU DO WSTRZYKIWAŃ	FR/H/0156/001	20031	LFB BIOMEDICAMENTS	PL
BETAFACT 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	FR/H/0156/001	2-00256	LFB BIOMEDICAMENTS	AT
BETAFACT 50 IU/ml, poeder en oplosmiddel voor oplossing voor injectie	FR/H/0156/001	RVG 24794	LFB BIOMEDICAMENTS	NL
BETAFACT 50 IU/mL, κόνις και διαλύτης για ενέσιμο διάλυμα	FR/H/0156/001	86513/16/06-11-2017	VIANEX S.A.	GR
BETAFACT 50 IU/mL, κόνις και διαλύτης για ενέσιμο διάλυμα	FR/H/0156/001	26150/14/06-11-2017	VIANEX S.A.	GR
BETAFACT 50 IU/mL, κόνις και διαλύτης για ενέσιμο διάλυμα	FR/H/0156/001	43725/14/06-11-2017	VIANEX S.A.	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
BETAFACT 50 NE/ml por és oldószer oldatos injekcióhoz	FR/H/0156/001	OGYI-T-22056/02	LFB BIOMEDICAMENTS	HU
BETAFACT 50 NE/ml por és oldószer oldatos injekcióhoz	FR/H/0156/001	OGYI-T-22056/01	LFB BIOMEDICAMENTS	HU
BETAFACT 50 NE/ml por és oldószer oldatos injekcióhoz	FR/H/0156/001	OGYI-T-22056/03	LFB BIOMEDICAMENTS	HU
BETAFACT 50 UI/ml pulbere și solvent pentru soluție injectabilă	FR/H/0156/001	4622/2012/02	LFB BIOMEDICAMENTS	RO
BETAFACT 50 UI/ml pulbere și solvent pentru soluție injectabilă	FR/H/0156/001	4622/2012/01	LFB BIOMEDICAMENTS	RO
BETAFACT 50 UI/ml pulbere și solvent pentru soluție injectabilă	FR/H/0156/001	4622/2012/03	LFB BIOMEDICAMENTS	RO
BETAFACT 50 UI/ml, polvo y disolvente para solución inyectable	FR/H/0156/001	75941	LFB BIOMEDICAMENTS	ES
BETAFACT 50 UI/ml, poudre et solvant pour solution injectable	FR/H/0156/001	34009 562 308 8 4	LFB BIOMEDICAMENTS	FR

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
BETAFACT 50 UI/ml, poudre et solvant pour solution injectable	FR/H/0156/001	34009 562 306 5 5	LFB BIOMEDICAMENTS	FR
BETAFACT 50 UI/ml, poudre et solvant pour solution injectable	FR/H/0156/001	34009 562 307 1 6	LFB BIOMEDICAMENTS	FR
BETAFACT 50 UI/ml, poudre et solvant pour solution injectable	not available	2010010649	LFB BIOMEDICAMENTS	LU
BETAFACT 50 UI/ml, poudre et solvant pour solution injectable	not available	2010010648	LFB BIOMEDICAMENTS	LU
BETAFACT 500 IU, PROSZEK I ROZPUSZCZALNIK DO SPORZĄDZANIA ROZTWORU DO WSTRZYKIWAŃ	FR/H/0156/001	20032	LFB BIOMEDICAMENTS	PL
BETAFACT, 50 UI/ml, pó e solvente para solução injetável	FR/H/0156/001	3095387	LFB BIOMEDICAMENTS	PT
BETAFACT, 50 UI/ml, pó e solvente para solução injetável	FR/H/0156/001	3095486	LFB BIOMEDICAMENTS	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
BETAFACT, 50 UI/ml, pó e solvente para solução injetável	FR/H/0156/001	3095288	LFB BIOMEDICAMENTS	PT
Factor IX Grifols 50 UI/ml polvo y disolvente para solución inyectable	not available	65916	INSTITUTO GRIFOLS, S.A.	ES
HaemoBionine 100 UI/ml Polvere e solvente per soluzione iniettabile	AT/H/0190/002	039072020	BIOTEST PHARMA GMBH	IT
HaemoBionine 100 UI/ml Polvere e solvente per soluzione iniettabile	AT/H/0190/002	039072032	BIOTEST PHARMA GMBH	IT
Haemonine 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	AT/H/0190/002	2-00348	BIOTEST PHARMA GMBH	AT
Haemonine 1000 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	AT/H/0190/002	PEI.H.03626.03.1	BIOTEST PHARMA GMBH	DE
Haemonine 500 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	AT/H/0190/002	PEI.H.03626.02.1	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
Haemonine® 1000 Powder and solvent for solution for injection	AT/H/0190/002	PL 04500/0008	BIOTEST PHARMA GMBH	UK
Haemonine® 500 Powder and solvent for solution for injection	AT/H/0190/002	PL 04500/0008	BIOTEST PHARMA GMBH	UK
Humafactor-9 1000 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-4849/05	HUMAN BIOPLAZMA MANUFACTURING AND TRADING LLC	HU
Humafactor-9 500 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-4849/04	HUMAN BIOPLAZMA MANUFACTURING AND TRADING LLC	HU
IXED 1000 UI/10 ml, polvere e solvente per soluzione per infusione	not available	041799038	KEDRION S.P.A.	IT
IXED 500 UI/10 ml, polvere e solvente per soluzione per infusione	not available	041799026	KEDRION S.P.A.	IT
Mononine , 500 j.m., proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań / infuzji	DE/H/1945/001	12466	CSL BEHRING GMBH	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
Mononine® 1000 I.E., 100 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/1945/002	2-00315	CSL BEHRING GMBH	AT
Mononine® 500 I.E., 100 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/1945/001	2-00314	CSL BEHRING GMBH	AT
Mononine 1000 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje	DE/H/1945/002	H/06/01052/002	CSL BEHRING GMBH	SI
Mononine 1000 IU 100 IU/ml prášok a rozpúšťadlo na injekčný alebo infúzny roztok	DE/H/1945/002	16/0006/06-S	CSL BEHRING GMBH	SK
Mononine 1000 NE, por és oldószer oldatos injekcióhoz vagy infúzióhoz	DE/H/1945/002	OGYI-T-20159/01	CSL BEHRING GMBH	HU
Mononine 1000 UI/10 ml, poudre et solvant pour solution injectable ou perfusion	DE/H/1945/002	NL 20918	CSL BEHRING GMBH	FR

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
MONONINE 1000, 100 UI/ml, polvo y disolvente para solución inyectable o perfusión	DE/H/1945/002	60.312	CSL BEHRING GMBH	ES
Mononine 1000, 1000 UI, pó e solvente para solução injetável ou para perfusão	DE/H/1945/002	2208684	CSL BEHRING GMBH	PT
Mononine 500 500 UI, pó e solvente para solução injetável ou para perfusão	DE/H/1945/001	2208585	CSL BEHRING GMBH	PT
Mononine 500 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje	DE/H/1945/001	H/06/01052/001	CSL BEHRING GMBH	SI
Mononine 500 IU 100 IU/ml prášok a rozpúšťadlo na injekčný alebo infúzny roztok	DE/H/1945/001	16/0005/06-S	CSL BEHRING GMBH	SK
Mononine 500 IU, 100 IU/ml, prášek a rozpouštědlo pro injekční/infuzní roztok	DE/H/1945/001	16/024/06-C	CSL BEHRING GMBH	CZ
Mononine 500 NE por és oldószer oldatos injekcióhoz vagy infúzióhoz	DE/H/1945/001	OGYI-T-20159/01	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
MONONINE 500 UI polvo y disolvente para solución inyectable/perfusión	DE/H/1945/001	60.311	CSL BEHRING GMBH	ES
Mononine, 1000 j.m., proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań / infuzji	DE/H/1945/002	12467	CSL BEHRING GMBH	PL
Mononine, 1000 U.I. Polvere e solvente per soluzione per iniezione / infusione	DE/H/1945/002	028142038	CSL BEHRING GMBH	IT
Mononine, 500 U.I. Polvere e solvente per soluzione per iniezione / infusione	DE/H/1945/001	028142026	CSL BEHRING GMBH	IT
Mononine, Poeder en oplosmiddel voor oplossing voor injectie of infusie 1000 IE	DE/H/1945/002	RVG16876	CSL BEHRING GMBH	NL
Mononine, poeder en oplosmiddel voor oplossing voor injectie of infusie 500 IE	DE/H/1945/001	RVG16875	CSL BEHRING GMBH	NL
Mononine® 100 IE/ml, pulver och vätska till injektions-/infusionsvätska, lösning	DE/H/1945/002	11970	CSL BEHRING GMBH	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
Mononine® 100 IE/ml, pulver och vätska till injektions-/infusionsvätska, lösning	DE/H/1945/001	11970	CSL BEHRING GMBH	SE
Mononine® 1000, 100 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/1945/002	26218.02.00	CSL BEHRING GMBH	DE
Mononine® 1000, 100 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/1945/002	1013/09010125	CSL BEHRING GMBH	LU
MONONINE® 500 UI/5 ml, poudre et solvant pour solution injectable ou perfusion	DE/H/1945/001	NL 20917	CSL BEHRING GMBH	FR
Mononine® 500, 100 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/1945/001	26218.01.00	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
Mononine® 500, 100 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	DE/H/1945/001	1013/09010124	CSL BEHRING GMBH	LU
Nanofix 1000 IE pulver och vätska till injektionsvätska, lösning	DE/H/0213/002	43527	OCTAPHARMA AB	SE
NanoFix 1000 IU, 1000 IU powder and solvent for solution for injection	DE/H/0213/002	PA2219/009/002	OCTAPHARMA (IP) SPRL	IE
Nanofix 500 IE pulver och vätska till injektionsvätska, lösning	DE/H/0213/001	43526	OCTAPHARMA AB	SE
NanoFix 500 IU, 500 IU powder and solvent for solution for injection	DE/H/0213/001	PA2219/009/001	OCTAPHARMA (IP) SPRL	IE
Nanofix, pulver og solvens til injektionsvæske, opløsning	DE/H/0213/002	46199	OCTAPHARMA AB	DK
Nanofix, pulver og solvens til injektionsvæske, opløsning	DE/H/0213/001	46198	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
Novix 50 UI/ml polvo y disolvente para solución inyectable	not available	65917	INSTITUTO GRIFOLS, S.A.	ES
OCTAFIX 100 UI / ml, poudre et solvant pour solution injectable	DE/H/0213/001	3400956341467	OCTAPHARMA FRANCE	FR
OCTAFIX 100 UI / ml, poudre et solvant pour solution injectable	DE/H/0213/002	3400956341528	OCTAPHARMA FRANCE	FR
OCTANINE 1000 UI, 1000 UI - polvere e solvente per soluzione iniettabile	DE/H/0213/002	040092025	OCTAPHARMA ITALY S.P.A.	IT
OCTANINE 500 IU, 500 IU powder and solvent for solution for injection	DE/H/0213/001	MA1219/00801	OCTAPHARMA (IP) SPRL	MT
OCTANINE 500 UI, 500 UI - polvere e solvente per soluzione iniettabile	DE/H/0213/001	040092013	OCTAPHARMA ITALY S.P.A.	IT
OCTANINE 100 IU/ml, 1 000 IU injektiokuva-aine ja liuotin, liuosta varten	DE/H/0213/002	16842	OCTAPHARMA AB	FI
OCTANINE 100 IU/ml, 500 IU injektiokuva-aine ja liuotin, liuosta varten	DE/H/0213/001	16842	OCTAPHARMA AB	FI

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
Octanine 100 UI/ml polvo y disolvente para solución inyectable	DE/H/0213/002	72466	OCTAPHARMA S.A.	ES
Octanine 100 UI/ml polvo y disolvente para solución inyectable	DE/H/0213/001	72466	OCTAPHARMA S.A.	ES
OCTANINE 1000 i.e. prašek in vehikel za raztopino za injiciranje	DE/H/0213/002	H/11/01144/001-002	OCTAPHARMA (IP) SPRL	SI
Octanine 1000 IE pulver og væske til injeksjonsvæske, oppløsning	DE/H/0213/002	09-7265	OCTAPHARMA AS	NO
OCTANINE 1000 IE, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0213/002	BE240037	OCTAPHARMA BENELUX S.A.	BE
OCTANINE 1000 IU, 1000 IU powder and solvent for solution for injection	DE/H/0213/002	MA1219/00802	OCTAPHARMA (IP) SPRL	MT
OCTANINE 1000 IU, 1000 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	DE/H/0213/002	PL 10673/0015	OCTAPHARMA-LTD	UK
OCTANINE 1000 IU, 1000 IU κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/0213/002	20944	OCTAPHARMA (IP) SPRL	CY

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
OCTANINE 1000 NE por és oldószer oldatos injekcióhoz	DE/H/0213/002	OGYI-T-20217/02	OCTAPHARMA (IP) SPRL	HU
OCTANINE 1000 SV pulveris un ģķidinātais injekciju ģķiduma pagatavošanai	DE/H/0213/002	10-0190	OCTAPHARMA (IP) SPRL	LV
octanine 1000 TV milteliai ir tirpiklis injekciniam tirpalui	DE/H/0213/002	LT/1/10/2098/002	OCTAPHARMA (IP) SPRL	LT
OCTANINE 1000 UI, poudre et solvant pour solution injectable	DE/H/0213/002	0311918	OCTAPHARMA BENELUX S.A.	LU
OCTANINE 500 i.e. prašek in vehikel za raztopino za injiciranje	DE/H/0213/001	H/11/01144/001-002	OCTAPHARMA (IP) SPRL	SI
Octanine 500 IE pulver og væske til injeksjonsvæske, oppløsning	DE/H/0213/001	09-7264	OCTAPHARMA AS	NO
OCTANINE 500 IE, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0213/001	BE240021	OCTAPHARMA BENELUX S.A.	BE
OCTANINE 500 IU, 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	DE/H/0213/001	PL 10673/0015	OCTAPHARMA-LTD	UK

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
OCTANINE 500 IU, 500 IU κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/0213/001	20943	OCTAPHARMA (IP) SPRL	CY
OCTANINE 500 NE por és oldószer oldatos injekcióhoz	DE/H/0213/001	OGYI-T-20217/01	OCTAPHARMA (IP) SPRL	HU
OCTANINE 500 SV pulveris un ģķidinatajs injekciju ģķiduma pagatavošanai	DE/H/0213/001	10-0191	OCTAPHARMA (IP) SPRL	LV
octanine 500 TV milteliai ir tirpiklis injekciniam tirpalui	DE/H/0213/001	LT/1/10/2098/001	OCTAPHARMA (IP) SPRL	LT
OCTANINE 500 UI, poudre et solvant pour solution injectable	DE/H/0213/001	0311904	OCTAPHARMA BENELUX S.A.	LU
OCTANINE F 500 Prášek a rozpouštedlo pro injekční roztok	DE/H/0213/001	75/492/93-A/C	OCTAPHARMA (IP) SPRL	CZ
Octanine F 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0213/002	2-00374	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanine F 100 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0213/001	2-00374	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
Octanine F 100 IU/ml prašak i otapalo za otopinu za injekciju	not available	HR-H-479880748	JANA PHARM D.O.O.	HR
Octanine F 100 IU/ml prašak i otapalo za otopinu za injekciju	not available	HR-H-479880748	JANA PHARM D.O.O.	HR
Octanine F 1000 I.U., 1000 IU prášek a rozpúšťadlo na injekčný roztok	DE/H/0213/002	16/0245/10-S	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	SK
OCTANINE F 1000 Prášek a rozpouštědlo pro injekční roztok	DE/H/0213/002	75/492/93- B/C	OCTAPHARMA (IP) SPRL	CZ
OCTANINE F 1000 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0213/002	10501A/97-3	OCTAPHARMA GMBH	DE
OCTANINE F 1000 UI pulbere și solvent pentru soluție perfuzabilă	DE/H/0213/002	7371/2015/01	OCTAPHARMA (IP) SPRL	RO
OCTANINE F 1000, 1000 J.M., PROSZEK I ROZPUSZCZALNIK DO SPORZĄDZANIA ROZTWORU DO WSTRZYKIWAŃ	DE/H/0213/002	17756	OCTAPHARMA (IP) SPRL	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
Octanine F 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	2-00254	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octanine F 500 I.U., 500 IU prášok a rozpúšťadlo na injekčný roztok	DE/H/0213/001	16/0244/10-S	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	SK
OCTANINE F 500 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0213/001	10501A/97-2	OCTAPHARMA GMBH	DE
OCTANINE F 500 UI pulbere și solvent pentru soluție perfuzabilă	DE/H/0213/001	7370/2015/01	OCTAPHARMA (IP) SPRL	RO
OCTANINE F 500, 500 J.M., PROSZEK I ROZPUSZCZALNIK DO SPORZĄDZANIA ROZTWORU DO WSTRZYKIWAŃ	DE/H/0213/001	17757	OCTAPHARMA (IP) SPRL	PL
OCTANINE, 1000 RÜ süstelahuse pulber ja lahusti	DE/H/0213/002	687710	OCTAPHARMA (IP) SPRL	EE
OCTANINE, 500 RÜ süstelahuse pulber ja lahusti	DE/H/0213/001	687610	OCTAPHARMA (IP) SPRL	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
OCTANINEF 1000 UI/10 ml pó e solvente para solução injetável	DE/H/0213/002	5284104	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
OCTANINEF 500 UI/5ml pó e solvente para solução injetável	DE/H/0213/001	5284070	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
АЙМАФИКС 500 IU прах и разтворител за инфузионен разтвор	not available	20040433	KEDRION S.P.A.	BG
Октанайн F 1000 IU, прах и разтворител за инжекционен разтвор	DE/H/0213/002	20100284	OCTAPHARMA (IP) SPRL	BG
Октанайн F 500 IU, прах и разтворител за инжекционен разтвор	DE/H/0213/001	20100283	OCTAPHARMA (IP) SPRL	BG