



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2017
EMA/45481/2017
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: human prothrombin complex

Procedure no.: PSUSA/00001638/201604



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
Confidex 1000 IU, injektiokuva-aine ja liuotin, liuosta varten	DE/H/0477/003	30897	CSL BEHRING GMBH	FI
Beriplex® P/N 250 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0477/001	2-00337	CSL BEHRING GMBH	AT
Beriplex® P/N 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	DE/H/0477/002	2-00338	CSL BEHRING GMBH	AT
Beriplex 500 UI, polvo y disolvente para solución para inyección	DE/H/0477/002	69890	CSL BEHRING GMBH	ES
Confidex 500UI, poudre et solvant pour solution injectable.	DE/H/0477/002	BE319742	CSL BEHRING GMBH	BE
Confidex 500IE, poeder en oplosmiddel voor oplossing voor injectie.	DE/H/0477/002	BE319742	CSL BEHRING GMBH	BE
Beriplex P/N 250 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung zur intravenösen Anwendung	DE/H/0477/001	10500A/95	CSL BEHRING GMBH	DE
Beriplex P/N 500 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung zur intravenösen Anwendung	DE/H/0477/002	10501A/95	CSL BEHRING GMBH	DE
Confidex 500 IU, injektiokuva-aine ja liuotin, liuosta varten	DE/H/0477/002	24125	CSL BEHRING GMBH	FI
Confidex 250 IU, injektiokuva-aine ja liuotin, liuosta varten	DE/H/0477/001	24124	CSL BEHRING GMBH	FI

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Confidex 250 UI, poudre et solvant pour solution injectable	DE/H/0477/001	NL34892	CSL BEHRING GMBH	FR
Confidex 500 UI, poudre et solvant pour solution injectable	DE/H/0477/002	NL34893	CSL BEHRING GMBH	FR
Beriplex P/N 250 IU, powder and solvent for solution for injection	DE/H/0477/001	PL 15036/0028	CSL BEHRING GMBH	UK
Beriplex P/N 500 IU, powder and solvent for solution for injection	DE/H/0477/002	PL 15036/0029	CSL BEHRING GMBH	UK
Beriplex P/N 500, κόνις και διαλύτης για ενέσιμο διάλυμα	DE/H/0477/002	39439/14-06-2010	CSL BEHRING MEPE	GR
Beriplex P/N 500 por és oldószer oldatos injekcióhoz	DE/H/0477/002	OGYI-T-6408/01	CSL BEHRING GMBH	HU
Confidex 500 Polvere e solvente per soluzione iniettabile	DE/H/0477/002	038844015	CSL BEHRING GMBH	IT
Confidex 500UI, poudre et solvant pour solution injectable.	DE/H/0477/002	1013/09100009	CSL BEHRING GMBH	LU
Confidex 500IE, poeder en oplosmiddel voor oplossing voor injectie.	DE/H/0477/002	1013/09100009	CSL BEHRING GMBH	LU
Beriplex P/N 500, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0477/002	RVG101094	CSL BEHRING GMBH	NL
Beriplex P/N 250, poeder en oplosmiddel voor oplossing voor injectie	DE/H/0477/002	RVG101080	CSL BEHRING GMBH	NL
Confidex 250 IE, pulver og væske til injeksjonsvæske, oppløsning	DE/H/0477-001	07/5241	CSL BEHRING GMBH	NO

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Confidex 500 IE, pulver og væske til injeksjonsvæske, oppløsning	DE/H/0477/002	07/5242	CSL BEHRING GMBH	NO
Beriplex P/N 250, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	DE/H/0477/001	15102	CSL BEHRING GMBH	PL
Beriplex P/N 500, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwań	DE/H/0477/002	15103	CSL BEHRING GMBH	PL
Beriplex 500 UI Pó e solvante para solução injectável	DE/H/0477/002	5087671	CSL BEHRING GMBH	PT
Confidex 500 IE, pulver och vätska till injektionsvätska, lösning	DE/H/0477/002	26080	CSL BEHRING GMBH	SE
Confidex 250 IE, pulver och vätska till injektionsvätska, lösning	DE/H/0477/001	26079	CSL BEHRING GMBH	SE
Beriplex P/N 500, 500 IU powder and solvent for solution for injection	DE/H/0477/002	20160002/07.01.2016	CSL BEHRING GMBH	BG
Beriplex P/N 1000, 1000 IU powder and solvent for solution for injection	DE/H/0477/003/DC	20160003/07.01.2016	CSL BEHRING GMBH	BG
Confidex, pulver og solvens til injektionsvæske, opløsning	DE/H/0477/001	56386	CSL BEHRING GMBH	DK
Confidex, pulver og solvens til injektionsvæske, opløsning	DE/H/0477/002	56387	CSL BEHRING GMBH	DK
Confidex, pulver og solvens til	DE/H/0477/003	56388	CSL BEHRING GMBH	DK

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injektionsvæske, opløsning				
Beriplex 500 IU, prášek a rozpouštědlo pro injekční roztok	DE/H/0477/002	75/088/16-C	CSL BEHRING GMBH	CZ
Beriplex 1000 IU, prášek a rozpouštědlo pro injekční roztok	DE/H/0477/003	75/089/16-C	CSL BEHRING GMBH	CZ
Confidex, pulver og solvens til injektionsvæske, opløsning	DE/H/0477/001	56386	CSL BEHRING GMBH	DK
Confidex, pulver og solvens til injektionsvæske, opløsning	DE/H/0477/002	56387	CSL BEHRING GMBH	DK
Confidex, pulver og solvens til injektionsvæske, opløsning	DE/H/0477/002	56388	CSL BEHRING GMBH	DK
Beriplex P/N 500 IU prašak i otapalo za otopinu za injekciju	DE/H/0477/002	HR-H-899027590	CSL BEHRING GMBH	HR
Beriplex P/N 1000 IU prašak i otapalo za otopinu za injekciju	DE/H/0477/003	HR-H-291305034	CSL BEHRING GMBH	HR
Beriplex P/N 250 IU, powder and solvent for solution for injection	DE/H/0477/001	PA 800/10/1	CSL BEHRING GMBH	IE
Beriplex P/N 500 IU, powder and solvent for solution for injection	DE/H/0477/002	PA 800/10/2	CSL BEHRING GMBH	IE
Beriplex P/N 1000 IU, powder and solvent for solution for injection	DE/H/0477/003	PA 800/10/3	CSL BEHRING GMBH	IE
Beriplex P/N 500 IU, powder and solvent for	DE/H/0477/002	MA665/00301	CSL BEHRING GMBH	MT

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solution for injection				
Beriplex P/N 1000 IU, powder and solvent for solution for injection	DE/H/0477/003	MA665/00302	CSL BEHRING GMBH	MT
Beriplex P/N 500 UI pulbere și solvent pentru soluție injectabilă	DE/H/0477/002	8626/2016/01	CSL BEHRING GMBH	RO
Beriplex P/N 1000 UI pulbere și solvent pentru soluție injectabilă	DE/H/0477/003	8627/2016/01	CSL BEHRING GMBH	RO
Beriplex 500 IU prášok a rozpúšťadlo na injekčný roztok	DE/H/0477/002	16/0250/16-S	CSL BEHRING GMBH	SK
Beriplex 1 000 IU prášok a rozpúšťadlo na injekčný roztok	DE/H/0477/003	16/0251/16-S	CSL BEHRING GMBH	SK
Confidex 1000 Polvere e solvente per soluzione iniettabile	DE/H/0477/003	038844027	CSL BEHRING GMBH	IT
Beriplex 1000 UI, polvo y disolvente para solución para inyección	DE/H/0477/003	76961	CSL BEHRING GMBH	ES
Beriplex P/N 1000 IU, powder and solvent for solution for injection	DE/H/0477/003	PL 15036/0034	CSL BEHRING GMBH	UK
Beriplex P/N 1000 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung zur intravenösen Anwendung	DE/H/0477/003/DC	10501A/95A	CSL BEHRING GMBH	DE
Beriplex P/N 1000 por és oldószer oldatos injekcióhoz	DE/H/0477/003	OGYI-T-6408/02	CSL BEHRING GMBH	HU
Beriplex® P/N 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer	DE/H/0477/003	2-00404	CSL BEHRING GMBH	AT

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Injektionslösung				
Confidex 1000UI, poudre et solvant pour solution injectable.	DE/H/0477/003	BE435461	CSL BEHRING GMBH	BE
Confidex 1000IE, poeder en oplosmiddel voor oplossing voor injectie.	DE/H/0477/003	BE435461	CSL BEHRING GMBH	BE
Beriplex P/N 1000 IE, poeder en oplosmiddel voor oplossing voor injectie.	DE/H/0477/003	IE RVG 112293	CSL BEHRING GMBH	NL
Confidex 1000 UI, poudre et solvant pour solution injectable	DE/H/0477/003	3400958516139	CSL BEHRING GMBH	FR
Beriplex P/N 1000, proszek i rozpuszczalnik do sporządzania roztworu do wstrzykiwan	DE/H/0477/003	21117	CSL BEHRING GMBH	PL
Confidex 1000UI, poudre et solvant pour solution injectable.	DE/H/0477/003	2013080268	CSL BEHRING GMBH	LU
Confidex 1000IE, poeder en oplosmiddel voor oplossing voor injectie.	DE/H/0477/003	2013080268	CSL BEHRING GMBH	LU
Beriplex P/N 1000, κόκκις και διαλύτης για ενέσιμο διάλυμα	DE/H/0477/003	52886/24-07-2013	CSL BEHRING MEPE	GR
PPSB Solvent Detergent Dubbel geïnactiveerd gelyofiliseerd humaan prothrombinecomplex	not available	BE188431	CAFDCF	BE
Proplex 600 IU powder and solvent for solution for injection	AT/H/0373/001	5363-I-1051/14	BAXTER D.O.O.	SI
Prothromplex Total NF, proszek i rozpuszczalnik do sporządzania roztworu	AT/H/0373/001	22169	BAXTER POLSKA SP Z O.O.	PL

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do wstrzykiwan, 600 j.m.				
Prothromplex I.E. 600 Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	AT/H/0373/01	BE461600	BAXALTA INNOVATIONS GMBH	BE
Prothromplex TOTAL 600 IU powder and solvent for solution for injection.	AT/H/0373/001	PA 2004/5/1	BAXALTA INNOVATIONS GMBH	IE
Prothromplex, pulver og solvens til injektionsvæske, opløsning	AT/H/0373/001	53742	BAXALTA INNOVATIONS GMBH	DK
Prothromplex, injektiokuiva-aine ja liuotin, liuosta varten.	AT/H/0373/001	32094	BAXALTA INNOVATIONS GMBH	FI
Prothromplex NF 600	AT/H/0373/001	PEI.H.11717.01.1	BAXALTA DEUTSCHLAND GMBH	DE
Prothromplex 600 IE, poeder en oplosmiddel voor oplossing voor injectie.	AT/H/0373/001	RVG 115018	BAXALTA INNOVATIONS GMBH	NL
Prothromplex 600 UI, poudre et solvant pour solution injectable	AT/H/0373/01	0774114	BAXALTA INNOVATIONS GMBH	LU
Prothromplex, 600 UI/20 ml pó e solvente para solução injetável	AT/H/0373/001	5622766	BAXALTA INNOVATIONS GMBH	PT
Prothromplex TOTAL 600 IU powder and solvent for solution for injection	AT/H/0373/001	PL 34078/0009	BAXALTA INNOVATIONS GMBH	UK
Prothromplex 600 IE pulver och vätska till injektionsvätska, lösning	AT/H/0373/001	50855	BAXALTA INNOVATIONS GMBH	SE
Prothromplex Total 600 UI, polvo y disolvente para solución inyectable	AT/H/0373/01	78913	BAXALTA SPAIN S.L.U	ES

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Prothromplex 600 IE pulver og væske til injeksjonsvæske, oppløsning.	AT/H/0373/001	10-7482	BAXALTA INNOVATIONS GMBH	NO
Prothromplex 600 UI, poudre et solvant pour solution injectable	AT/H/0373/01	BE461600	BAXALTA INNOVATIONS GMBH	BE
PROTHROMPLEX TOTAL NF Prášek a rozpouštědlo pro injekční roztok	not available	75/474/93-C	BAXTER AG	CZ
PROTHROMPLEX, 600 RÜ süstelahuse pulber ja lahusti.	AT/H/0373/001	849714	BAXALTA INNOVATIONS GMBH	EE
Prothromplex 600 SV pulveris un šķīdinātājs injekciju šķīduma pagatavošanai	AT/H/0373/001	14-0208	BAXALTA INNOVATIONS GMBH	LV
Prothromplex 600 TV milteliai ir tirpiklis injekciniam tirpalui	AT/H/0373/001	LT/1/14/3611/001	BAXALTA INNOVATIONS GMBH	LT
PROTHROMPLEX NF 600 IU Ludský protrombínový komplex	AT/H/0373/001	16/0392/14-S	BAXALTA INNOVATIONS GMBH	SK
PROPLEX 600 UI polvere e solvente per soluzione iniettabile	AT/H/0373/001	043304017	BAXALTA INNOVATIONS GMBH	IT
Prothromplex TOTAL 600 IU powder and solvent for solution for injection	AT/H/0373/001	MA 1047/00201	BAXALTA INNOVATIONS GMBH	MT
Prothromplex Total 600 NE por és oldószer oldatos injekcióhoz Liofilizált, gőzzel kezelt, teljes humán prothrombinkomplex	not available	OGYI-T-4320/01	BAXALTA INNOVATIONS GMBH	HU
Протромплекс Тотал NF 600 IU прах и	AT/H/0373/001	9900411	BAXALTA INNOVATIONS GMBH	BG

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разтворител за инжекционен разтвор, Prothromplex Total NF 600 IU powder and solvent for solution for injection				
Prothromplex TOTAL 600 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	AT/H/0373/001	2-00312	BAXTER AG	AT
Prothromplex TOTAL 600 IU, κόνις και διαλύτης για ενέσιμο διάλυμα	AT/H/0373/001	4156	BAXTER (HELLAS)	GR
Prothromplex TOTAL 600 UI pulbere și solvent pentru soluție injectabilă	AT/H/0373/01	7176/2014/01	BAXALTA INNOVATIONS GMBH	RO
Cofact 500 UI, poudre et solvant pour solution injectable.	NL/H/0859/002	BE300036	SANQUIN PLASMA PRODUCTS B.V.	BE
Cofact 500 UI, poudre et solvant pour solution injectable.	NL/H/0859/002	571-053-9	SANQUIN PLASMA PRODUCTS B.V.	FR
Cofact 500 UI, poudre et solvant pour solution injectable.	NL/H/0859/002	1527/07090007	SANQUIN PLASMA PRODUCTS B.V.	LU
Cofact 500 IE, poeder en oplosmiddel voor oplossing voor injectie.	NL/H/0859/002	RVG 17060	SANQUIN PLASMA PRODUCTS B.V.	NL
Cofact 500 IE, poeder en oplosmiddel voor oplossing voor injectie.	NL/H/0859/002	BE300036	SANQUIN PLASMA PRODUCTS B.V.	BE
Cofact 500 I.E. Prothrombinkomplex vom Menschen, 500 I.E. Faktor IX pro Durchstechflasche Pulver und Lösungsmittel	NL/H/0859/002	2-00326	SANQUIN PLASMA PRODUCTS B.V.	AT

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zur Herstellung einer Injektionslösung				
Cofact 250 a.e., stungulyfsstofn og leysir, lausn.	NL/H/0859/	IS/1/14/104/01-02	SANQUIN PLASMA PRODUCTS B.V.	IS
Cofact 500 a.e., stungulyfsstofn og leysir, lausn.	NL/H/0859/	IS/1/14/104/01-02	SANQUIN PLASMA PRODUCTS B.V.	IS
Cofact 250 IE, poeder en oplosmiddel voor oplossing voor injectie	NL/H/0859	RVG 17060	SANQUIN PLASMA PRODUCTS B.V.	NL
Cofact 500 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	NL/H/0859/001	PEI.H.03453.02.1	SANQUIN PLASMA PRODUCTS B.V.	DE
Cofact 250 UI, poudre et solvant pour solution injectable.	NL/H/0859/001	BE300027	SANQUIN PLASMA PRODUCTS B.V.	BE
Cofact 250 IU, injektiokuiva-aine ja liuotin, liuosta varten. Cofact 500 IU, injektiokuiva-aine ja liuotin, liuosta varten.	NL/H/0859/	22397	SANQUIN PLASMA PRODUCTS B.V.	FI
Cofact 250 I.E. Prothrombinkomplex vom Menschen, 250 I.E. Faktor IX pro Durchstechflasche Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	NL/H/0859/001	2-00325	SANQUIN PLASMA PRODUCTS B.V.	AT
Cofact 250 IE, poeder en oplosmiddel voor oplossing voor injectie.	NL/H/0859/001	BE300027	SANQUIN PLASMA PRODUCTS B.V.	BE
Cofact 250 UI, poudre et solvant pour solution injectable.	NL/H/859/001-002/	1527/07090006, 1527/07090007	SANQUIN PLASMA PRODUCTS B.V.	LU

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Cofact 500 UI, poudre et solvant pour solution injectable.				
Cofact 250 UI, poudre et solvant pour solution injectable. Cofact 500 UI, poudre et solvant pour solution injectable.	NL/H/0859/	571-052-2	SANQUIN PLASMA PRODUCTS B.V.	FR
PPSB Solvent Detergent Complexe prothrombique humain cryodesséché doublement inactivé	not available	0435316	CAFDCF	LU
PPSB Solvent Detergent Complexe prothrombique humain cryodesséché doublement inactivé	not available	BE188431	CAFDCF	BE
PPSB Solvent Detergent Dubbel geïnactiveerd gelyofiliseerd humaan prothrombinecomplex	not available	BE188431	CAFDCF	BE
UMAN COMPLEX 500 UI/20 ml polvere e solvante per soluzione per infusione	not available	023309103	KEDRION S.P.A.	IT
UMAN COMPLEX 500 IU powder and solvent for solution for infusion	not available	20040521	KEDRION S.P.A.	BG
KEDCOM 500 UI/20 ml polvere e solvante per soluzione per infusione	not available	041850013	KEDRION S.P.A.	IT
Cofact 250 UI, poudre et solvant pour solution injectable. Cofact 500 UI, poudre et solvant pour solution injectable.	NL/H/0859/	571-052-2	SANQUIN PLASMA PRODUCTS B.V.	FR

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Octaplex 500 IU prašak i otapalo za otopinu za infuziju	not available	HR-H-107880130	JANA PHARM D.O.O.	HR
Octaplex	DE/H/0464/001	5363-I-1048/14	OCTAPHARMA (IP)-LTD.	SI
OCTAPLEX 500 I.E. PULVER UND LÖSUNGSMITTEL ZUR HERSTELLUNG EINER INFUSIONSLÖSUNG	DE/H/0464/001	2-00307	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octaplex 500 UI poudre et solvant pour solution pour perfusion	DE/H/0464/001	BE305401	OCTAPHARMA BENELUX S.A./N.V.	BE
ОКТАПЛЕКС 500 IU, ПРАХ И РАЗТВОРИТЕЛ ЗА ИНФУЗИО	DE/H/0464/001	20090134	OCTAPHARMA (IP)-LTD.	BG
OCPLEX, 500 IU PRÁ A ROZPOU INFUZNÍ ROZTOK ☐ T	DE/H/0464/001	16/059/07-C	OCTAPHARMA (IP)-LTD.	CZ
OCTAPLEX, PULVER OG SOLVENS TIL INFUSIONSVÆSKE, OPLØSNING	DE/H/0464/001	44424	OCTAPHARMA AB	DK
OCTAPLEX, 500 RÜ, INFUSIONILAHUSE PULBER JA LAHUSTI	DE/H/0464/001	521206	OCTAPHARMA (IP)-LTD.	EE
Octaplex, 500 IU, infuusiokuiva-aine ja liuotin, liuosta varten	DE/H/0464/001	21938	OCTAPHARMA AB	FI
ОКТАПЛЕКС 1000 IU, ПРАХ И РАЗТВОРИТЕЛ ЗА ИНФУЗИО	DE/H/0464/002	20150272	OCTAPHARMA (IP)-LTD.	BG
OCTAPLEX 1000 PULVER UND LÖSUNGSMITTEL ZUR HERSTELLUNG EINER I.V. INFUSIONSLÖSUNG	DE/H/0464/002	PEI.H.02312.02.1	OCTAPHARMA GMBH	DE
Octaplex 1000 IU powder and solvent for solution	DE/H/0464/002	PL 10673/0041	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
for infusion				
OCTAPLEX 500 PULVER UND LÖSUNGSMITTEL ZUR HERSTELLUNG EINER I.V. INFUSIONSLÖSUNG	DE/H/0464/001	PEI.H.02312.01.1	OCTAPHARMA GMBH	DE
Octaplex 500 UI, poudre et solvant pour solution pour perfusion	DE/H/0464/001	566 106-0 (NEW 3400956610600)	OCTAPHARMA FRANCE	FR
Octaplex, 500 IU, Κόνις και διαλύτης για διάλυμα προς έγχυση	DE/H/0464/001	7775/2-2-2010	OCTAPHARMA HELLAS A.E.	GR
Octaplex 500 NE por és oldószer oldatos infúzióhoz	DE/H/0464/001	OGYI-T-20295/01	OCTAPHARMA (IP)-LTD.	HU
Octaplex	DE/H/0464/001	IS/1/09/040/01	OCTAPHARMA AB	IS
Octaplex 500 IU coagulation factor IX per vial, powder and solvent for solution for infusion	DE/H/0464/001	PA 521/13/1	OCTAPHARMA-LTD	IE
Pronativ, 500 UI, polvere e solvente per soluzione per infusione	DE/H/0464/001	AIC N° 039240015	OCTAPHARMA ITALY S.P.A.	IT
Octaplex 500 TV milteliai ir tirpiklis infuziniam tirpalui	DE/H/0464/001	LT/1/07/0781/001	OCTAPHARMA (IP)-LTD.	LT
Octaplex 500 SV pulveris un □ķīdinātājs infūziju □ķīduma pagatavo□anai	DE/H/0464/001	06-0225	OCTAPHARMA (IP)-LTD.	LV
Octaplex, 500 IE poeder en oplosmiddel voor oplossing voor infusie	DE/H/0464/001	RVG 30499	OCTAPHARMA GMBH	NL
Octaplex 500 j.m. proszek i rozpuszczalnik do sporządzania roztworu do infuzji	DE/H/0464/001	12767	OCTAPHARMA (IP)-LTD.	PL
OCTAPLEX, 500 UI, Polvo	DE/H/0464/001	66447	OCTAPHARMA S.A.	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
y disolvente para solución para perfusión				
Octaplex 500 IU powder and solvent for solution for infusion	DE/H/0464/001	PL 10673/0027	OCTAPHARMA-LTD	UK
Pronativ 500 UI pulbere și solvent pentru soluție perfuzabilă	DE/H/0464/001	7802/2015/01	OCTAPHARMA (IP)-LTD.	RO
Ocplex 500 IE pulver och vätska till infusionsvätska, lösning	DE/H/0464/001	20462	OCTAPHARMA AB	SE
Octaplex 500 IU prá rozpuštění roztok	DE/H/0464/001	16/0401/06-S	OCTAPHARMA (IP)-LTD.	SK
OCTAPLEX, 1000 RÜ, INFUSIOONILAHUSE PULBER JA LAHUSTI	DE/H/0464/002	885915	OCTAPHARMA (IP)-LTD.	EE
Octaplex, 1000 UI, pó e solvante para solução para perfusão	DE/H/0464/002	5658331	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
OCTAPLEX, PULVER OG SOLVENS TIL INFUSIONSVÆSKE, OPLØSNING	DE/H/0464/002	54862	OCTAPHARMA AB	DK
Ocplex 1000 IE pulver och vätska till infusionsvätska, lösning	DE/H/0464/002	51858	OCTAPHARMA AB	SE
Octaplex 500 UI poudre et solvant pour solution pour perfusion	DE/H/0464/001	0376926	OCTAPHARMA BENELUX S.A./N.V.	LU
Octaplex 500 IE pulver og væske til infusionsvæske, oppløsning	DE/H/0464/001	08-6421	OCTAPHARMA AG	NO
Octaplex, 500 UI, pó e solvante para solução para perfusão	DE/H/0464/001	5260369	OCTAPHARMA PRODUTOS FARMACEUTICOS, 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
OCTAPLEX 1000 I.E. PULVER UND LÖSUNGSMITTEL ZUR HERSTELLUNG EINER INFUSIONSLÖSUNG	DE/H/0464/002	236525	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Octaplex 1000 SV pulveris un ☐ hidinātājs ☐ ķiduma pagatavošanai	DE/H/0464/002	15-0257	OCTAPHARMA (IP)-LTD.	LV
Octaplex 1000 IE, poeder en oplosmiddel voor oplossing voor infusie	DE/H/0464/002	RVG 116220	OCTAPHARMA GMBH	NL
Octaplex 1000 IE pulver og væske til infusionsvæske, oppløsning	DE/H/0464/002	14/10321	OCTAPHARMA AG	NO
Octaplex 1000 TV milteliai ir tirpiklis infuziniam tirpalui	DE/H/0464/002	LT/1/07/0781/002	OCTAPHARMA (IP)-LTD.	LT
Octaplex 1000 UI poudre et solvant pour solution pour perfusion	DE/H/0464/002	BE478320	OCTAPHARMA BENELUX S.A./N.V.	BE
Ocplex 1000 IU, prášek a rozpouštědlo pro infuzní roztok	DE/H/0464/002	75/502/15-C	OCTAPHARMA (IP)-LTD.	CZ
Octaplex, 1000 j.m., proszek i rozpuszczalnik do sporządzania roztworu do infuzji	DE/H/0464/002	22730	OCTAPHARMA (IP)-LTD.	PL
Pronativ, 1000 UI, polvere e solvente per soluzione per infusione	DE/H/0464/002	AIC N. 039240027	OCTAPHARMA ITALY S.P.A.	IT
Octaplex 1000 IU coagulation factor IX per vial, powder and solvent for solution for infusion	DE/H/0464/002	PA0521/013/002	OCTAPHARMA-LTD	IE
Octaplex, 1000 IU, infuusiokuiva-aine ja	DE/H/0464/002	32668	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
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Octaplex 1000 a.e. innrennslisstofn og leysir, lausn	DE/H/0464/002	IS/1/15/101/01	OCTAPHARMA AB	IS
Octaplex 1000 NE por és oldószer oldatos infúzióhoz	DE/H/0464/002	OGYI-T-20295/02	OCTAPHARMA (IP)-LTD.	HU
Pronativ 1000 UI pulbere și solvent pentru soluție perfuzabilă	DE/H/0464/002	8245/2015/01	OCTAPHARMA (IP)-LTD.	RO
OCTAPLEX, 1000 UI, Polvo y disolvente para solución para perfusión	DE/H/0464/002	80417	OCTAPHARMA S.A.	ES
Octaplex 1000 UI poudre et solvant pour solution pour perfusion	DE/H/0464/002	2016040064	OCTAPHARMA BENELUX S.A./N.V.	LU
Octaplex 1000 UI, poudre et solvant pour solution pour perfusion	DE/H/0464/002	34009 550 151 0 9	OCTAPHARMA FRANCE	FR