01 September 2017
EMA/562354/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): antithrombin iii

Procedure No.: PSUSA/00003159/201612

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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
ACLOTINE 100 UI/ml, poudre et solvant pour solution injectable	not available	561 938-8	LFB BIOMEDICAMENTS	FR
ACLOTINE 100 UI/ml, poudre et solvant pour solution injectable	not available	561 937-1	LFB BIOMEDICAMENTS	FR
Anbinex 1000 U.I. pó e solvente para solução para perfusão	not available	3807286	INSTITUTO GRIFOLS, S.A.	PT
Anbinex 1000 UI Polvere e solvente per soluzione per infusione	not available	034330047	INSTITUTO GRIFOLS, S.A.	IT
Anbinex 50 IU/ml, prášek a rozpouštědlo pro injekční roztok	not available	75/221/90-C	INSTITUTO GRIFOLS, S.A.	CZ
Anbinex 50 UI/ml Polvo y disolvente para solución para perfusión	not available	59259	INSTITUTO GRIFOLS, S.A.	ES
Anbinex 500 IU, 1000 IU, prášok a rozpúšťadlo na injekčný roztok	not available	75/0221/90-C/S	INSTITUTO GRIFOLS, S.A.	SK
Anbinex 500 U. I. pó e solvente para solução para perfusão.	not available	3807187	INSTITUTO GRIFOLS, S.A.	PT
Anbinex 500 UI Polvere e solvente per soluzione per infusione	not available	034330035	INSTITUTO GRIFOLS, S.A.	IT
Anbinex, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	9405	INSTITUTO GRIFOLS, S.A.	PL
Anbinex, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	9406	INSTITUTO GRIFOLS, S.A.	PL
Anbinex® 500 I.E. und Anbinex® 1000 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung	not available	7812.00.00	GRIFOLS DEUTSCHLAND GMBH	DE
Antithrombin III "Baxter" 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	2-00339	BAXTER AG	AT
ANTITHROMBIN III BAXALTA 1000 IU prášok a rozpúštadlo na injekcný/infúzny roztokLudský antitrombín III získaný z plazmy	not available	16/0226/13-S	BAXALTA INNOVATIONS 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
Antithrombin III BAXALTA 50 IU/ml powder and solvent for solution for injection/infusion - АНТИТРОМБИН III NF БАКСТЕР 50 IU/ml, прах и разтворител за инжекционен/инфузионен разтвор	not available	9700502	BAXALTA INNOVATIONS GMBH	BG
ANTITHROMBIN III BAXALTA 50 IU/ml, powder and solvent for solution for injection or infusion	not available	MA 1047/00101-2	BAXALTA INNOVATIONS GMBH	MT
ANTITHROMBIN III BAXALTA 500 IU prášok a rozpúšťadlo na injekčný/infúzny roztokĽudský antitrombín III získaný z plazmy	not available	16/0144/89-C/S	BAXALTA INNOVATIONS GMBH	SK
ANTITHROMBIN III BAXALTA, prášek a rozpouštědlo pro infuzní roztok	not available	16/144/89-C	BAXALTA INNOVATIONS GMBH	CZ
Antithrombin III Baxter 50 IU/ml prašak i otapalo za otopinu za injekciju/infuziju	not available	HR-H-812546421	AGMAR D.O.O.	HR
Antithrombin III Baxter pulver och vätska till injektions-/infusionsvätska, lösning	not available	11236	BAXALTA INNOVATIONS GMBH	SE
ANTITHROMBIN III KONZENTRAT BAXALTA, 50 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektionslösung oder Infusionslösung	not available	BE274005	BAXALTA INNOVATIONS GMBH	BE
ANTITHROMBIN III KONZENTRAT BAXALTA, 50 I.E./ml, Pulver und Lösungsmittel zur Herstellung einer Injektionslösung oder Infusionslösung	not available	BE273971	BAXALTA INNOVATIONS GMBH	BE
Antithrombin III NF Baxalta, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	R/3024	BAXALTA POLAND SP. Z O.O.	PL

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Antithrombin III NF Baxalta, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	R/3025	BAXALTA POLAND SP. Z O.O.	PL
Antitrombin III Baxalta, pulver og solvens til injektions- eller infusionsvæske, opløsning	not available	12587	BAXALTA INNOVATIONS GMBH	DK
ANTITROMBINA III BAXALTA 1000 UI/20 ml, pó e solvente para solução injectável	not available	4791182	BAXALTA INNOVATIONS GMBH	PT
ANTITROMBINA III BAXALTA 500 UI/10 ml, pó e solvente para solução injectável	not available	4791083	BAXALTA INNOVATIONS GMBH	PT
ANTITROMBINA III BAXALTA, polvere e solvente per soluzione per infusione	not available	027113012	BAXALTA INNOVATIONS GMBH	IT
ANTITROMBINA III BAXALTA, polvere e solvente per soluzione per infusione	not available	027113024	BAXALTA INNOVATIONS GMBH	IT
ANTITROMBINE III CONCENTRAAT BAXALTA 500 IE en 1000 IE.	not available	RVG17433	BAXALTA INNOVATIONS GMBH	NL
ANTITROMBINE III-CONCENTRAAT BAXALTA, 1000 IE/ml, poeder en oplosmiddel voor oplossing voor injectie of intraveneuze infusie.	not available	BE274005	BAXALTA INNOVATIONS GMBH	BE
ANTITROMBINE III-CONCENTRAAT BAXALTA, 50 IE/ml, poeder en oplosmiddel voor oplossing voor injectie of intraveneuze infusie.	not available	BE273971	BAXALTA INNOVATIONS GMBH	BE
AT III KEDRION 1000 UI/20 ml Polvere e solvente per soluzione per infusione	not available	029378027	KEDRION S.P.A.	IT
AT III KEDRION 2000 UI/40 ml Polvere e solvente per soluzione per infusione	not available	029378039	KEDRION 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
AT III KEDRION 500 UI/10 ml Polvere e solvente per soluzione per infusione	not available	029378015	KEDRION S.P.A.	IT
AT III NF 1000	not available	7208.03.00	BAXALTA DEUTSCHLAND GMBH	DE
AT III NF 1000	not available	7208.03.00	BAXALTA DEUTSCHLAND GMBH	DE
AT III NF 500	not available	7208.02.00	BAXALTA DEUTSCHLAND GMBH	DE
AT III NF 500	not available	7208.02.00	BAXALTA DEUTSCHLAND GMBH	DE
Atenativ	DK/H/1016/001	10813 (500 IU)	OCTAPHARMA AB	DK
Atenativ	DK/H/1016/001	10813 (1000 IU)	OCTAPHARMA AB	DK
Atenativ	not available	17259/16-02-2016 (1000 IU)	OCTAPHARMA HELLAS A.E.	GR
Atenativ	not available	17258/16-02-2016 (500 IU)	OCTAPHARMA HELLAS A.E.	GR
Atenativ 1000 I.E. - Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00081 (1000 IU)	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Atenativ 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	not available	4310.00.00 (1000 IU)	OCTAPHARMA GMBH	DE
Atenativ 1000 IE pulver og væske til infusjonsvæske, oppløsning	not available	03-1958 (1000 IU)	OCTAPHARMA AB	NO
Atenativ 1000 IU	not available	9035 (1000 IU)	OCTAPHARMA AB	FI
ATENATIV 1000 UI, polvo y disolvente para solución para perfusión	not available	58544 (1000 IU)	OCTAPHARMA S.A.	ES
Atenativ 1000 UI/20 ml polvere e solvente per soluzione per infusione endovenosa	not available	031118021 (1000 IU)	OCTAPHARMA AB	IT
Atenativ 50 IE/ml pulver och vätska till infusionsvätska, lösning	not available	09887-3 (1000 IU)	OCTAPHARMA AB	SE
Atenativ 50 IE/ml pulver och vätska till infusionsvätska, lösning	not available	09887-1 (500 IU)	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
Atenativ 50 IU/ml prašak i otapalo za otopinu za injekciju/ infuziju	not available	HR-H-973250138 (500 IU)	JANA PHARM D.O.O.	HR
Atenativ 50 IU/ml prašak i otapalo za otopinu za injekciju/ infuziju	not available	HR-H-973250138 (1000 IU)	JANA PHARM D.O.O.	HR
Atenativ 50 NE/ml por és oldószer oldatos infúzióhoz vagy injekcióhoz	not available	OGYI-T-1565/01 (500 IU)	OCTAPHARMA AB	HU
Atenativ 50 NE/ml por és oldószer oldatos infúzióhoz vagy injekcióhoz	not available	OGYI-T-1565/02 (1000 IU)	OCTAPHARMA AB	HU
Atenativ 50 UI/ml, pó e solvente para solução injetável	not available	4789582 (500 IU)	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Atenativ 50 UI/ml, pó e solvente para solução injetável	not available	4789681 (1000 IU)	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Atenativ 500 I.E. - Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00080 (500 IU)	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Atenativ 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	not available	4310.00.00 (500 IU)	OCTAPHARMA GMBH	DE
Atenativ 500 IE pulver og væske til infusjonsvæske, oppløsning	not available	6943 (500 IU)	OCTAPHARMA AB	NO
Atenativ 500 IU	not available	9035 (500 IU)	OCTAPHARMA AB	FI
ATENATIV 500 U.I., polvo y disolvente para solución para perfusión	not available	58301 (500 IU)	OCTAPHARMA S.A.	ES
Atenativ 500 UI/10 ml polvere e solvente per soluzione per infusione endovenosa	not available	031118019 (500 IU)	OCTAPHARMA AB	IT
Atenativ, 50 IU/ml, prášok a rozpú adlo na infúzny roztok	DK/H/1016/001	16/0124/08-S (1000 IU)	OCTAPHARMA (IP)-LTD.	SK
Atenativ, 50 IU/ml, prá ok a rozpú adlo na infúzny roztok	DK/H/1016/001	16/0124/08-S (500 IU)	OCTAPHARMA (IP)-LTD.	SK
Atenativ, 50 IU/ml, prášek a rozpouštědlo pro infuzní roztok	DK/H/1016/001	16/266/08-C (1000 IU)	OCTAPHARMA (IP)-LTD.	CZ
Atenativ, 50 IU/ml, prášek a rozpouštědlo pro infuzní roztok	DK/H/1016/001	16/266/08-C (500 IU)	OCTAPHARMA (IP)-LTD.	CZ

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Atenativ, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	DK/H/1016/001	14708 (500 IU)	OCTAPHARMA (IP)-LTD.	PL
Atenativ, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	DK/H/1016/001	14708 (1000 IU)	OCTAPHARMA (IP)-LTD.	PL
Atenativ, poeder voor infusievloeistof 1000 IE	not available	RVG 17400 (1000 IU)	OCTAPHARMA GMBH	NL
Atenativ, poeder voor infusievloeistof 500 IE	not available	RVG 17400 (500 IU)	OCTAPHARMA GMBH	NL
ATKED 1000 UI/ 20 ml, polvere e solvente per soluzione per infusione	not available	041800020	KEDRION S.P.A.	IT
ATKED 2000 UI/ 40 ml, polvere e solvente per soluzione per infusione	not available	041800032	KEDRION S.P.A.	IT
ATKED 500 UI/ 10 ml, polvere e solvente per soluzione per infusione	not available	041800018	KEDRION S.P.A.	IT
Concentré d'Antithrombine III Baxalta 1000 UI/ml, poudre et solvant pour solution injectable ou pour perfusion	not available	BE274005	BAXALTA INNOVATIONS GMBH	BE
Concentré d'Antithrombine III Baxalta 50 UI/ml, poudre et solvant pour solution injectable ou pour perfusion	not available	BE273971	BAXALTA INNOVATIONS GMBH	BE
Kybernin ? P 500 / 1000 IU	not available	75/0131/84-C/S	CSL BEHRING GMBH	SK
Kybernin ? P 500 / 1000 IU	not available	75/0131/84-C/S	CSL BEHRING GMBH	SK
Kybernin 50 NE/ml por és oldószer oldatos injekcióhoz vagy infúzióhoz	not available	OGYI-T-5237/01	CSL BEHRING GMBH	HU
Kybernin P Prášek a rozpouštedlo pro injekcní/infuzní roztok. 500 IU / 1000 IU	not available	75/131/84-C	CSL BEHRING GMBH	CZ
Kybernin P 1000 U.I. polvere e solvente per soluzione per infusione	not available	025766027	CSL BEHRING GMBH	IT

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Kybernin P 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	7543	CSL BEHRING GMBH	PL
Kybernin P 500 i.e. prašek in vehikel za raztopino za injiciranje ali infundiranje	not available	5363-I-729/10	CSL BEHRING GMBH	SI
Kybernin P 500 prašak za otopinu za injekciju ili infuziju	not available	UP/I-530-09/12-02/304	CSL BEHRING GMBH	HR
Kybernin P 500 U.I. polvere e solvente per soluzione per infusione	not available	025766039	CSL BEHRING GMBH	IT
Kybernin P* 500 I.E./1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00052	CSL BEHRING GMBH	AT
Kybernin P* 500 I.E./1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00052	CSL BEHRING GMBH	AT
Kybernin P® 500/1000	not available	5258/27-01-2010	CSL BEHRING MEPE	GR
Kybernin P® 500/1000	not available	5257/27-01-2010	CSL BEHRING MEPE	GR
Kybernin® P 1000 Pulver (weißes Lyophilisat) zur intravenösen Injektion oder Infusion nach Auflösung mit zugehörigem Lösungsmittel.	not available	13101.01.00	CSL BEHRING GMBH	DE
KYBERNIN® P 1000 UI	not available	57.357	CSL BEHRING, S.A	ES
Kybernin® P 500 Pulver (weißes Lyophilisat) zur intravenösen Injektion oder Infusion nach Auflösung mit zugehörigem Lösungsmittel.	not available	13101.00.00	CSL BEHRING GMBH	DE
KYBERNIN® P 500 UI	not available	57.356	CSL BEHRING, 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
Kybernin® P 500/1000 Pulver (weißes Lyophilisat) zur intravenösen Injektion oder Infusion nach Auflösung mit zugehörigem Lösungsmittel	not available	0062955	CSL BEHRING GMBH	LU
Kybernin® P 500/1000 Pulver (weißes Lyophilisat) zur intravenösen Injektion oder Infusion nach Auflösung mit zugehörigem Lösungsmittel	not available	0062969	CSL BEHRING GMBH	LU
Kybernin®P 500/1000	not available	3321783	CSL BEHRING GMBH	PT
Kybernin®P 500/1000	not available	3321684	CSL BEHRING GMBH	PT