



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 September 2026
EMADOC-1700519818-3436694
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): antithrombin III

EURD list No. PSUSA/00003159/202512



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 i.e. prašek in vehikel za raztopino za injiciranje/infundiranje	not available	H/93/00863/001	CSL BEHRING GMBH	SI
Kybernin P 1000 UI polvo y disolvente para solución inyectable y para perfusión	not available	57.357	CSL BEHRING S.A.	ES
Kybernin P 500 UI polvo y disolvente para solución inyectable y para perfusión	not available	57.356	CSL BEHRING S.A.	ES
Kybernin P 1000 UI polvo y disolvente para solución inyectable y para perfusión	not available	57.357	CSL BEHRING S.A.	ES
Kybernin P 500 UI polvo y disolvente para solución inyectable y para perfusión	not available	57.356	CSL BEHRING S.A.	ES
Anbinex® 500 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung Wirkstoff: Antithrombin vom Menschen	not available	7812.00.00	GRIFOLS DEUTSCHLAND GMBH	DE
Anbinex® 1000 I.E., Trockensubstanz und Lösungsmittel zur Herstellung einer Injektionslösung Wirkstoff: Antithrombin vom Menschen	not available	7812.00.00	GRIFOLS DEUTSCHLAND GMBH	DE
ATENATIV 50 UI/mL,	DK/H/1016/001	2024030064	OCTAPharma BENELUX S.A.	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
poudre et solvant pour solution pour perfusion				
ATENATIV 50 UI/mL, poudre et solvant pour solution pour perfusion	DK/H/1016/001	2024030064	OCTAPHARMA BENELUX S.A.	LU
Atenativ 50 UI/ml pulbere și solvent pentru soluție perfuzabilă	DK/H/1016/001	15636/2024/01	OCTAPHARMA (IP) SPRL	RO
Atenativ 50 UI/ml pulbere și solvent pentru soluție perfuzabilă	DK/H/1016/001	15636/2024/02	OCTAPHARMA (IP) SPRL	RO
Atenativ, 50 IU/ml, prášek a rozpouštědlo pro infuzní roztok	DK/H/1016/001	16/266/08-C	OCTAPHARMA (IP) SPRL	CZ
Atenativ, 50 IU/ml, prášek a rozpouštědlo pro infuzní roztok	DK/H/1016/001	16/266/08-C	OCTAPHARMA (IP) SPRL	CZ
Atenativ, pulver og solvens til infusionsvæske, opløsning	DK/H/1016/001	10813	OCTAPHARMA AB	DK
Atenativ, pulver og solvens til infusionsvæske, opløsning	DK/H/1016/001	10813	OCTAPHARMA AB	DK
Atenativ, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	DK/H/1016/001	14708	OCTAPHARMA (IP) SPRL	PL
Atenativ, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	DK/H/1016/001	14708	OCTAPHARMA (IP) SPRL	PL
Atenativ, 50 IU/ml, prášek a rozpouštědlo	DK/H/1016/001	16/0124/08-S	OCTAPHARMA (IP) SPRL	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
na infūzny roztok				
Atenativ, 50 IU/ml, práok a rozpúťadlo na infūzny roztok	DK/H/1016/001	16/0124/08-S	OCTAPHARMA (IP) SPRL	SK
Atenativ 50 SV/ml, pulveris un ķīdinātājs infūziju ķīduma pagatavošanai	DK/H/1016/001	19-0199	OCTAPHARMA (IP) SPRL	LV
Atenativ 50 SV/ml, pulveris un ķīdinātājs infūziju ķīduma pagatavošanai	DK/H/1016/001	19-0199	OCTAPHARMA (IP) SPRL	LV
Atenativ 50 RŪ/ml, infusioonilahuse pulber ja lahusti	DK/H/1016/001	998119	OCTAPHARMA (IP) SPRL	EE
Atenativ 50 RŪ/ml, infusioonilahuse pulber ja lahusti	DK/H/1016/001	998119	OCTAPHARMA (IP) SPRL	EE
Atenativ 50 i.e./ml prašek in vehikel za raztopino za infundiranje	DK/H/1016/001	H/19/02679/001	OCTAPHARMA (IP) SPRL	SI
Atenativ 50 i.e./ml prašek in vehikel za raztopino za infundiranje	DK/H/1016/001	H/19/02679/002	OCTAPHARMA (IP) SPRL	SI
Atenativ 50 TV/ml milteliai ir tirpiklis infuziniam tirpalui	DK/H/1016/001	LT/1/20/4501/001	OCTAPHARMA (IP) SPRL	LT
Atenativ 50 TV/ml milteliai ir tirpiklis infuziniam tirpalui	DK/H/1016/001	LT/1/20/4501/002	OCTAPHARMA (IP) SPRL	LT
ATENATIV 50 UI/mL, poudre et solvant pour solution pour perfusion	DK/H/1016/001	34009 302 019 4 7	OCTAPHARMA FRANCE	FR
ATENATIV 50 UI/mL, poudre et solvant pour	DK/H/1016/001	34009 302 019 5 4	OCTAPHARMA FRANCE	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
solution pour perfusion				
ANTITROMBINE III CONCENTRAAT BAXALTA 500 IE, poeder en oplosmiddel voor injectie of intraveneuze infusie	not available	RVG 17433	BAXALTA INNOVATIONS GMBH	NL
ANTITHROMBIN III BAXALTA 1000 IU prášok a rozpúšťadlo na injekčný/infúzny roztok Ľudský antitrombín III získaný z plazmy	not available	16/0226/13-S	BAXALTA INNOVATIONS GMBH	SK
ANTITHROMBIN III BAXALTA 500 IU prášok a rozpúšťadlo na injekčný/infúzny roztok Ľudský antitrombín III získaný z plazmy	not available	16/0144/89-C/S	BAXALTA INNOVATIONS GMBH	SK
Attertium "500 UI/10 ml Polvere e solvente per soluzione per infusione"	not available	044565012	GRIFOLS ITALIA S.P.A	IT
Attertium "1000 UI/20 ml Polvere e solvente per soluzione per infusione"	not available	044565024	GRIFOLS ITALIA S.P.A	IT
Atenativ 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	not available	4310.00.00	OCTAPHARMA GMBH	DE
Atenativ 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Infusionslösung	not available	4310.00.00	OCTAPHARMA GMBH	DE
Kybernin P 1000 IU Prášok a rozpúšťadlo na	not available	75/0065/18-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				
Kybernin P 500 IU Prášok a rozpúšťadlo na injekčný/infúzny roztok	not available	75/0131/84-C/S	CSL BEHRING GMBH	SK
Anbinex 1000 IU, prášok a rozpúšťadlo na injekčný roztok	not available	75/0221/90-C/S	INSTITUTO GRIFOLS, S.A.	SK
Anbinex 500 IU, prášok a rozpúšťadlo na injekčný roztok	not available	75/0221/90-C/S	INSTITUTO GRIFOLS, S.A.	SK
Kybernin® P 1000 Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	not available	13101.01.00	CSL BEHRING GMBH	DE
Kybernin® P 500 Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	not available	13101.00.00	CSL BEHRING GMBH	DE
Kybernin 50 NE/ml por és oldószer oldatos injekcióhoz vagy infúzióhoz	not available	OGYI-T-5237/01	CSL BEHRING GMBH	HU
ATENATIV 500 U.I., polvo y disolvente para solución para perfusión	not available	58301	OCTAPHARMA S.A.	ES
ATENATIV 1000 U.I., polvo y disolvente para solución para perfusión	not available	58544	OCTAPHARMA S.A.	ES
Anbinex 500 UI Polvere e solvente per soluzione per infusione	not available	034330035	INSTITUTO GRIFOLS, S.A.	IT
Anbinex 1000 UI Polvere e solvente per soluzione	not available	034330047	INSTITUTO GRIFOLS, S.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
per infusione				
Kybernin P 500 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00052	CSL BEHRING GMBH	AT
Kybernin P 1000 I.E. Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00052	CSL BEHRING GMBH	AT
Kybernin P 500 IU prášek a rozpouštědlo pro injekční/infuzní roztok	not available	75/131/84-C	CSL BEHRING GMBH	CZ
Kybernin P 1000 IU prášek a rozpouštědlo pro injekční/infuzní roztok	not available	75/131/84-C	CSL BEHRING GMBH	CZ
Antitrombin III "Baxalta", pulver og solvens til injektions- eller infusionsvæske, opløsning	not available	12587	BAXALTA INNOVATIONS GMBH	DK
Antitrombin III "Baxalta", pulver og solvens til injektions- eller infusionsvæske, opløsning	not available	12587	BAXALTA INNOVATIONS GMBH	DK
Atenativ 1000 I.E. - Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	2-00081	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Atenativ 500 I.E. -	not available	2-00080	OCTAPHARMA	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
Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung			PHARMAZEUTIKA PRODUKTIONSGESMBH	
Atenativ, 500 U.I./10 ml, pó e solvente para solução para perfusão	not available	4789582	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Atenativ, 1000 U.I./20 ml, pó e solvente para solução para perfusão	not available	4789681	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Antithrombin III NF Takeda, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	R/3024	TAKEDA PHARMA SP. Z O.O.	PL
Antithrombin III NF Takeda, 50 j.m./ml, proszek i rozpuszczalnik do sporządzania roztworu do infuzji	not available	R/3025	TAKEDA PHARMA SP. Z O.O.	PL
ANTITHROMBIN III KONZENTRAT BAXALTA, 1000 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektionslösung oder Infusionslösung.	not available	BE274005	BAXALTA INNOVATIONS GMBH	BE
ANTITHROMBIN III KONZENTRAT BAXALTA, 500 I.E., Pulver und Lösungsmittel zur Herstellung einer Injektionslösung oder Infusionslösung.	not available	BE273971	BAXALTA INNOVATIONS GMBH	BE
ANTITROMBINE III-	not available	BE274005	BAXALTA INNOVATIONS	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
CONCENTRAAT BAXALTA, 1000 IE, poeder en oplosmiddel voor oplossing voor injectie of infusie.			GMBH	
ANTITROMBINE III- CONCENTRAAT BAXALTA, 500 IE, poeder en oplosmiddel voor oplossing voor injectie of infusie.	not available	BE273971	BAXALTA INNOVATIONS GMBH	BE
CONCENTRE D'ANTITHROMBINE III BAXALTA, 500 UI, poudre et solvant pour solution injectable ou pour perfusion	not available	BE273971	BAXALTA INNOVATIONS GMBH	BE
CONCENTRE D'ANTITHROMBINE III BAXALTA, 1000 UI, poudre et solvant pour solution injectable ou pour perfusion	not available	BE274005	BAXALTA INNOVATIONS GMBH	BE
AT III KEDRION 500 UI/10 ml Polvere e solvente per soluzione per infusione	not available	029378015	KEDRION S.P.A.	IT
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
Atenativ 500 UI/10 ml polvere e solvente per soluzione per infusione endovenosa	not available	031118019	OCTAPHARMA (IP) SPRL	IT
Atenativ 1000 UI/20 ml polvere e solvente per soluzione per infusione endovenosa	not available	031118021	OCTAPHARMA (IP) SPRL	IT
Kybernin P 500 U.I. polvere e solvente per soluzione per infusione	not available	025766039	CSL BEHRING GMBH	IT
Kybernin P 1000 U.I. polvere e solvente per soluzione per infusione	not available	025766027	CSL BEHRING GMBH	IT
KYBERNIN P 500 j.m. Proszek i rozpuszczalnik do sporządzania roztworu do infuzji, 50 j.m./ml.	not available	7543	CSL BEHRING GMBH	PL
Atenativ 50 IU/ml prašak i otapalo za otopinu za injekciju/ infuziju	not available	HR-H-973250138	JANA PHARM D.O.O.	HR
Atenativ 50 IU/ml prašak i otapalo za otopinu za injekciju/ infuziju	not available	HR-H-973250138	JANA PHARM D.O.O.	HR
АНТИТРОМБИН III NF БАКСАЛТА антитромбин III, получен от човешка плазма	not available	9700502	BAXALTA INNOVATIONS GMBH	BG
АНТИТРОМБИН III NF БАКСАЛТА антитромбин III, получен от човешка	not available	9700502	BAXALTA INNOVATIONS GMBH	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
плазма				
ACLOTINE 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 561 938 8 2	LFB BIOMEDICAMENTS	FR
ACLOTINE 100 UI/mL, poudre et solvant pour solution injectable	not available	34009 561 937 1 4	LFB BIOMEDICAMENTS	FR
Antithrombin III Baxalta 50 IU/ml prašak i otapalo za otopinu za injekciju/infuziju	not available	HR-H-812546421	BAXALTA INNOVATIONS GMBH	HR
Antithrombin III Baxalta 50 IU/ml prašak i otapalo za otopinu za injekciju/infuziju	not available	HR-H-812546421	BAXALTA INNOVATIONS GMBH	HR
Atenativ 500 IE pulver og væske til infusjonsvæske, oppløsning	not available	6943	OCTAPHARMA AB	NO
Atenativ 1000 IE pulver og væske til infusjonsvæske, oppløsning	not available	03-1958	OCTAPHARMA AB	NO
Antithrombin III Baxalta pulver och vätska till injektions-/infusionsvätska, lösning	not available	11236	BAXALTA INNOVATIONS GMBH	SE
Antithrombin III Baxalta pulver och vätska till injektions-/infusionsvätska, lösning	not available	11236	BAXALTA INNOVATIONS GMBH	SE
Anbinex 50 UI/ml Polvo y disolvente para solución para perfusión.	not available	59259	INSTITUTO GRIFOLS, S.A.	ES
Anbinex 50 UI/ml Polvo	not available	59259	INSTITUTO GRIFOLS, 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.				
ANTITHROMBIN III BAXALTA 500 NE por és oldószer oldatos injekcióhoz illetve infúzióhoz	not available	OGYI-T-2119/01	BAXALTA INNOVATIONS GMBH	HU
ANTITHROMBIN III BAXALTA 1000 NE por és oldószer oldatos injekcióhoz illetve infúzióhoz	not available	OGYI-T-2119/02	BAXALTA INNOVATIONS GMBH	HU
ANTITROMBINA III BAXALTA 50 UI/ml, polvere e solvente per soluzione per infusione	not available	027113012	BAXALTA INNOVATIONS GMBH	IT
ANTITROMBINA III BAXALTA 50 UI/ml, polvere e solvente per soluzione per infusione	not available	027113024	BAXALTA INNOVATIONS GMBH	IT
Antithrombin III „Takeda“ 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	2-00339	TAKEDA MANUFACTURING AUSTRIA AG	AT
Antithrombin III „Takeda“ 50 I.E./ml Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	2-00339	TAKEDA MANUFACTURING AUSTRIA AG	AT
Atenativ 50 NE/ml por és oldószer oldatos infúzióhoz vagy injekcióhoz	not available	OGYI-T-1565/01	OCTAPHARMA AB	HU
Atenativ 50 NE/ml por és	not available	OGYI-T-1565/02	OCTAPHARMA AB	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
oldószer oldatos infúzióhoz vagy injekcióhoz				
Anbinex 500 U. I. pó e solvente para solução injetável	not available	3807187	INSTITUTO GRIFOLS, S.A.	PT
Anbinex 1000 U.I. pó e solvente para solução injetável	not available	3807286	INSTITUTO GRIFOLS, S.A.	PT
ATKED 500 UI/ 10 ml polvere e solvente per soluzione per infusione	not available	041800018	KEDRION S.P.A.	IT
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
Anbinex 50 IU/ml, prášek a rozpouštědlo pro injekční roztok	not available	75/221/90-C	INSTITUTO GRIFOLS, S.A.	CZ
Anbinex 50 IU/ml, prášek a rozpouštědlo pro injekční roztok	not available	75/221/90-C	INSTITUTO GRIFOLS, S.A.	CZ
Atenativ 500 IU Infuusiokuiva-aine ja liuotin, liuosta varten	not available	9035	OCTAPHARMA AB	FI
Atenativ 1000 IU Infuusiokuiva-aine ja liuotin, liuosta varten	not available	9035	OCTAPHARMA AB	FI
Atenativ, poeder voor infusievloeistof 500 IE	not available	RVG 17400	OCTAPHARMA GMBH	NL
Atenativ, poeder voor infusievloeistof 1000 IE	not available	RVG 17400	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
Kybernin P 1000 IU Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση	not available	5258/27-01-2010	CSL BEHRING E.P.E.	GR
Kybernin P 500 IU Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση	not available	5257/27-01-2010	CSL BEHRING E.P.E.	GR
ANTITHROMBIN III BAXALTA 50 IU/ml prášek a rozpouštědlo pro infuzní roztok	not available	16/144/89-C	BAXALTA INNOVATIONS GMBH	CZ
ANTITHROMBIN III BAXALTA 50 IU/ml prášek a rozpouštědlo pro infuzní roztok	not available	16/144/89-C	BAXALTA INNOVATIONS GMBH	CZ
Kybernin® P 500 Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	not available	2007029198	CSL BEHRING GMBH	LU
Kybernin® P 1000 Pulver und Lösungsmittel zur Herstellung einer Injektions- / Infusionslösung	not available	2007029199	CSL BEHRING GMBH	LU
ANTITHROMBIN III BAXALTA 50 IU/ml, powder and solvent for solution for injection or infusion	not available	MA 1047/00101	BAXALTA INNOVATIONS GMBH	MT
ANTITHROMBIN III BAXALTA 50 IU/ml,	not available	MA 1047/00102	BAXALTA INNOVATIONS 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
powder and solvent for solution for injection or infusion				
Kybernin P 500 prašak za otopinu za injekciju ili infuziju	not available	HR-H-749555894	CSL BEHRING GMBH	HR
Kybernin P 1000 UI Pó e solvente para solução injetável ou para perfusão	not available	3321783	CSL BEHRING GMBH	PT
Kybernin P 500 UI Pó e solvente para solução injetável ou para perfusão	not available	3321684	CSL BEHRING GMBH	PT
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