



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 September 2022
EMA/382258/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Flumazenil

Procedure no.: PSUSA/00001413/202112

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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
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
Anexate 0,1 mg/ml oldatos injekció	not available	OGYI-T-1465/01	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
Anexate 0,1 mg/ml oldatos injekció	not available	OGYI-T-1465/01	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
Anexate 0,1 mg/ml oldatos injekció	not available	OGYI-T-1465/01	CHEPLAPHARM ARZNEIMITTEL GMBH	HU
Anexate 0,1 mg/ml soluție injectabilă	not available	8409/2015/01	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Anexate 0,1 mg/ml soluție injectabilă	not available	8409/2015/01	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Anexate 0,1 mg/ml soluție injectabilă	not available	8409/2015/01	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Anexate 0,1 mg/ml soluție injectabilă	not available	8409/2015/01	CHEPLAPHARM ARZNEIMITTEL GMBH	RO
Anexate 0,5 mg - Injektionslösung	not available	1-18341	CHEPLAPHARM ARZNEIMITTEL 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
Anexate 0,5 mg/5 ml Injektionlösung	not available	BE140226	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Anexate 0,5 mg/5 ml oplossing voor injectie	not available	BE140226	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Anexate 0,5 mg/5 ml otopina za injekciju/infuziju	not available	HR-H-700996011	CHEPLAPHARM ARZNEIMITTEL GMBH	HR
Anexate 0,5 mg/5 ml solución inyectable	not available	57.806	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Anexate 0,5 mg/5 ml solución inyectable	not available	57.806	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Anexate 0,5 mg/5 ml solución inyectable	not available	57.806	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Anexate 0,5 mg/5 ml solution injectable	not available	BE140226	CHEPLAPHARM ARZNEIMITTEL GMBH	BE
Anexate 0,5 mg/5 ml soluzione iniettabile per uso endovenoso	not available	026749010	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Anexate 0,5 mg/5 ml soluzione iniettabile per uso endovenoso	not available	026749010	CHEPLAPHARM ARZNEIMITTEL 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
ANEXATE 0,5 mg/5 ml, solution injectable (I.V.)	not available	355 758-8	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 0,5 mg/5 ml, solution injectable (I.V.)	not available	355 757-1	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 0,5 mg/5 ml, solution injectable (I.V.)	not available	355 759-4	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 0,5 mg/5 ml, solution injectable (I.V.)	not available	355 762-5	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 0,5 mg/5 ml, solution injectable (I.V.)	not available	355 761-9	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 0,5 mg/5 ml, solution injectable (I.V.)	not available	355 760-2	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
Anexate 1 mg - Injektionslösung	not available	1-18342	CHEPLAPHARM ARZNEIMITTEL GMBH	AT
Anexate 1 mg/10 ml solución inyectable	not available	57.807	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Anexate 1 mg/10 ml solución inyectable	not available	57.807	CHEPLAPHARM ARZNEIMITTEL 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
Anexate 1 mg/10 ml solución inyectable	not available	57.807	CHEPLAPHARM ARZNEIMITTEL GMBH	ES
Anexate 1 mg/10 ml soluzione iniettabile per uso endovenoso	not available	026749034	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
Anexate 1 mg/10 ml soluzione iniettabile per uso endovenoso	not available	026749034	CHEPLAPHARM ARZNEIMITTEL GMBH	IT
ANEXATE 1 mg/10 ml, solution injectable (I.V.)	not available	355 763-1	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 1 mg/10 ml, solution injectable (I.V.)	not available	355 765-4	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 1 mg/10 ml, solution injectable (I.V.)	not available	355 768-3	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 1 mg/10 ml, solution injectable (I.V.)	not available	355 766-0	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 1 mg/10 ml, solution injectable IV	not available	355 764-8	CHEPLAPHARM ARZNEIMITTEL GMBH	FR
ANEXATE 1 mg/10 ml, solution injectable IV	not available	355 767-7	CHEPLAPHARM ARZNEIMITTEL 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
Anexate 1,0 mg/10 ml oplossing voor injectie	not available	RVG 12857	CHEPLAPHARM ARZNEIMITTEL GMBH	NL
Anexate 1,0 mg/10 ml oplossing voor injectie	not available	RVG 12857	CHEPLAPHARM ARZNEIMITTEL GMBH	NL
Anexate 1,0 mg/10 ml oplossing voor injectie	not available	RVG 12857	CHEPLAPHARM ARZNEIMITTEL GMBH	NL
Anexate 100 mikrogramov/ml raztopina za injiciranje ali infundiranje	not available	H/93/00196/001	CHEPLAPHARM ARZNEIMITTEL GMBH	SI
Anexate 500 micrograms/5ml, solution for injection or infusion.	not available	PA 1868/002/001	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Anexate 500 micrograms/5ml, solution for injection or infusion.	not available	PA 1868/002/001	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Anexate 500 micrograms/5ml, solution for injection or infusion.	not available	PA 1868/002/001	CHEPLAPHARM ARZNEIMITTEL GMBH	IE
Anexate, 0,5 mg/5 ml oplossing voor injectie	not available	RVG 12857	CHEPLAPHARM ARZNEIMITTEL 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
Anexate, 0,5 mg/5 ml oplossing voor injectie	not available	RVG 12857	CHEPLAPHARM ARZNEIMITTEL GMBH	NL
Anexate, 0,5 mg/5 ml oplossing voor injectie	not available	RVG 12857	CHEPLAPHARM ARZNEIMITTEL GMBH	NL
Anexate® 0,5 mg/5 ml AMP ενέσιμο διάλυμα	not available	70795/17/24-06-2019	CHEPLAPHARM ARZNEIMITTEL GMBH	GR
Anexate® 0,5 mg/5 ml AMP ενέσιμο διάλυμα	not available	70795/17/24-06-2019	CHEPLAPHARM ARZNEIMITTEL GMBH	GR
Anexate® 0,5 mg/5 ml Injektionslösung	not available	14747.00.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Anexate® 1 mg/10 ml Injektionslösung	not available	14747.01.00	CHEPLAPHARM ARZNEIMITTEL GMBH	DE
Flumazenil B. Braun 0,1 mg/ml injektioneste, liuos	NL/H/0915/001	22559	B.BRAUN MELSUNGEN AG	FI
Flumazenil B. Braun 0,1 mg/ml Injektionslösung	NL/H/0915/001	BE296231	B.BRAUN MELSUNGEN AG	BE
Flumazenil B. Braun 0,1 mg/ml Injektionslösung	NL/H/0915/001	BE296222	B.BRAUN MELSUNGEN AG	BE

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Flumazenil B. Braun 0,1 mg/ml Injektionslösung	NL/H/0915/001	BE296231	B.BRAUN MELSUNGEN AG	BE
Flumazenil B. Braun 0,1 mg/ml Injektionslösung	NL/H/0915/001	BE296222	B.BRAUN MELSUNGEN AG	BE
Flumazenil B. Braun 0,1 mg/ml Injektionslösung und Konzentrat zur Herstellung einer Infusionslösung	NL/H/0915/001	64945.00.00	B.BRAUN MELSUNGEN AG	DE
Flumazenil B. Braun 0,1 mg/ml injektionsvätska, lösning	NL/H/0915/001	22559	B.BRAUN MELSUNGEN AG	FI
Flumazenil B. Braun 0,1 mg/ml solución inyectable EFG	NL/H/0915/001	69020	B.BRAUN MELSUNGEN AG	ES
Flumazenil B. Braun 0,1 mg/ml solution injectable	NL/H/0915/001	BE296231	B.BRAUN MELSUNGEN AG	BE
Flumazenil B. Braun 0,1 mg/ml solution injectable	NL/H/0915/001	BE296222	B.BRAUN MELSUNGEN AG	BE
Flumazenil B. Braun 0,1 mg/ml, oplossing voor injectie	NL/H/0915/001	BE296231	B.BRAUN MELSUNGEN AG	BE

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Flumazenil B. Braun 0,1 mg/ml, oplossing voor injectie	NL/H/0915/001	BE296222	B.BRAUN MELSUNGEN AG	BE
Flumazenil B. Braun, 0,1 mg/ml, roztwór do wstrzykiwań	NL/H/0915/001	14618	B.BRAUN MELSUNGEN AG	PL