



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2019
EMA/249447/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: rabbit anti-human T-lymphocyte immunoglobulin

Procedure no.: PSUSA/00010252/201806

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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
Grafalon 20 mg/ml concentrate for solution for infusion	not available	PA1015/001/001	NEOVII BIOTECH GMBH	IE
Thymoglobuline 25 mg prašak za otopinu za infuziju	not available	UP/I-530-09/13-02/183	SANOFI-AVENTIS CROATIA D.O.O.	HR
Thymoglobuline 5 mg/ml pulbere pentru soluție perfuzabilă	not available	7562/2015/01	GENZYME EUROPE B.V.	RO
THYMOGLOBULINE 25 mg, κόκκις διάλυμα προς έγχυση	not available	18403/15-03-13	GENZYME EUROPE B.V.	GR
Thymoglobuline 25 mg pulveris infūziju šķīduma pagatavošanai	not available	96-0045	GENZYME EUROPE B.V.	LV
THYMOGLOBULINE 5 mg/ml poeder voor oplossing voor infusie	not available	RVG 19204	GENZYME EUROPE B.V.	NL
Thymoglobuline 5 mg/ml, pulver til infusjonsvæske, oppløsning	not available	96-1728	GENZYME EUROPE B.V.	NO
Thymoglobuline 5 mg/ml, 25 mg, proszek do sporządzania roztworu do infuzji	not available	R/0312	GENZYME EUROPE B.V.	PL
Timoglobulina 25 mg/5ml pó para concentrado para solução para perfusão	not available	2528784	GENZYME EUROPE B.V.	PT
THYMOGLOBULINE 5 mg/ml, prášok na infúzny roztok	not available	59/0222/89-C/S	GENZYME EUROPE B.V.	SK
Thymoglobuline 5 mg/ml	not available	13195	GENZYME EUROPE B.V.	SE

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pulver till infusionsvätska, lösning				
THYMOGLOBULINE 5 mg/ml poeder voor oplossing voor infusie	not available	BE137611	GENZYME EUROPE B.V.	BE
THYMOGLOBULINE 5 mg/ml poudre pour solution pour perfusion	not available	BE137611	GENZYME EUROPE B.V.	BE
THYMOGLOBULINE 5 mg/ml poudre pour solution pour perfusion	not available	0398551	GENZYME EUROPE B.V.	LU
THYMOGLOBULINE 5 mg/ml poudre pour solution pour perfusion	not available	34009 570 281 8 3	GENZYME EUROPE B.V.	FR
Thymoglobuline 5 mg/ml, Pulver zur Herstellung einer Infusionslösung	not available	191A/92	GENZYME EUROPE B.V.	DE
Timoglobulina 5 mg/ml, polvo para solución para perfusion	not available	62650	GENZYME EUROPE B.V.	ES
Thymoglobuline 25 mg milteliai infuziniam tirpalui	not available	LT/1/04/3459/001	GENZYME EUROPE B.V.	LT
Thymoglobuline, 25 mg infusioonilahuse pulber	not available	223598	GENZYME EUROPE B.V.	EE
Thymoglobulin 25 mg por oldatos infúzióhoz	not available	OGYI-T-8997/01	GENZYME EUROPE B.V.	HU
THYMOGLOBULINE 5mg/ml, polvere per soluzione per infusione	not available	'033177027	GENZYME EUROPE B.V.	IT
Thymoglobuline 5 mg/ml - Pulver zur Herstellung einer Infusionslösung	not available	2-00167	GENZYME EUROPE B.V.	AT

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Thymoglobuline 5 mg/ml, prášek pro infuzní roztok	not available	59/222/89-C	GENZYME EUROPE B.V.	CZ
Thymoglobuline, pulver til infusionsvæske, opløsning	not available	15021	GENZYME EUROPE B.V.	DK
Thymoglobuline 5 mg/ml infuusiokuiva-aine, liuosta varten	not available	12474	GENZYME EUROPE B.V.	FI
GRAFALON 20 mg/ml concentrat pentru soluție perfuzabilă	not available	7711/2015/01	NEOVII BIOTECH GMBH	RO
GRAFALON 20 mg/ml concentrat pentru soluție perfuzabilă	not available	7711/2015/02	NEOVII BIOTECH GMBH	RO
Grafalon 20 mg/ml, koncentrát pro infuzní roztok	not available	59/256/97-C	NEOVII BIOTECH GMBH	CZ
Grafalon, 20 mg/ml infusioonilahuse kontsentraat	not available	431004	NEOVII BIOTECH GMBH	EE
Grafalon 20 mg/ml concentrado para solución para perfusión	not available	62.759	NEOVII BIOTECH GMBH	ES
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	560 884-1	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	560 885-8	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	560 886-4	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml,	not available	560 887-0	NEOVII BIOTECH GMBH	FR

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solution à diluer pour perfusion				
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	34009 560 884 1 6	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	34009 560 885 8 4	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	34009 560 886 4 5	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml, solution à diluer pour perfusion	not available	34009 560 887 0 6	NEOVII BIOTECH GMBH	FR
Grafalon 20 mg/ml concentrate for solution for infusion	not available	17186	NEOVII BIOTECH GMBH	CY
Grafalon 20 mg/ml concentraat voor oplossing voor infusie	not available	BE 137873	NEOVII BIOTECH GMBH	BE
Grafalon 20 mg/ml solution à diluer pour perfusion	not available	BE 137873	NEOVII BIOTECH GMBH	BE
Grafalon 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	BE 137873	NEOVII BIOTECH GMBH	BE
Grafalon 20 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/98/2648/001	NEOVII BIOTECH GMBH	LT
Grafalon 20 mg/ml koncentratas infuziniam tirpalui	not available	LT/1/98/2648/002	NEOVII BIOTECH GMBH	LT
Grafalon 20 mg/ml	not available	7331	NEOVII BIOTECH GMBH	PL

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koncentrat do sporządzania roztworu do infuzji				
Grafalon 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	2-00242	NEOVII BIOTECH GMBH	AT
Grafalon SCT 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0478/001	235079	NEOVII BIOTECH GMBH	AT
Grafalon 20 mg/ml concentrato per soluzione per infusione	AT/H/0478/001	042421014	NEOVII BIOTECH GMBH	IT
Grafalon 20 mg/ml concentrato per soluzione per infusione	AT/H/0478/001	042421026	NEOVII BIOTECH GMBH	IT
Grafalon 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	not available	452A/87	NEOVII BIOTECH GMBH	DE
Grafalon 20 mg/ml koncentrāts infūziju šķīduma pagatavošanai	not available	03-0091	NEOVII BIOTECH GMBH	LV
Grafalon 20 mg/ml concentraat voor oplossing voor infusie	not available	RVG 17602	NEOVII BIOTECH GMBH	NL
Grafalon 20 mg/ml koncentrat za raztopino za infundiranje	not available	H/04/00202/001	NEOVII BIOTECH GMBH	SI
Grafalon 20 mg/ml koncentrat till infusionsvätska, lösning	not available	14214	NEOVII BIOTECH GMBH	SE
Grafalon 20 mg/ml	not available	UP/-530-09/13-02/71	NEOVII BIOTECH GMBH	HR

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koncentrat za otopinu za infuziju				
Grafalon, 20 mg/ml, Concentrado para solução para perfusão	not available	3543485	NEOVII BIOTECH GMBH	PT
Grafalon, 20 mg/ml, Concentrado para solução para perfusão	not available	3543584	NEOVII BIOTECH GMBH	PT
Grafalon, 20 mg/ml, Concentrado para solução para perfusão	not available	3543782	NEOVII BIOTECH GMBH	PT
Grafalon, 20 mg/ml, Concentrado para solução para perfusão	not available	3543881	NEOVII BIOTECH GMBH	PT
Grafalon, 20 mg/ml infúzny koncentrát	not available	59/0229/01 –S	NEOVII BIOTECH GMBH	SK
Grafalon 20 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-8999/01	NEOVII BIOTECH GMBH	HU
Grafalon 20 mg/ml koncentrátum oldatos infúzióhoz	not available	OGYI-T-8999/02	NEOVII BIOTECH GMBH	HU