



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/150150/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: rabbit anti-human thymocyte (concentrate for solution for infusion)

Procedure no.: PSUSA/00010252/201506



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
Anti-T-Limfocitni Imunoglobulin Fresenius (future name: Grafalon)		H/04/00202/001	Medias International D.O.O. (Local MAH For Fresenius Biotech Gmbh)	Slovenia
Atg Neovii (future name: Grafalon)		03-0091	Neovii Biotech Gmbh	Latvia
Atg-Fresenius		LT/1/98/2648/001 \$ LT/1/98/2648/002	Neovii Biotech Gmbh	Lithuania
Atg-Fresenius (future name: Grafalon)		017186	C. A. Papaellina & Co Ltd (Local MAH For Fresenius Biotech Gmbh)	Cyprus
Atg-Fresenius (future name: Grafalon)		OGYI-T-8999/01 \$ OGYI-T-8999/02	Fresenius Medical Care Magyarország Egészségügyi Kft. (Local MAH For Fresenius Biotech Gmbh)	Hungary
Atg-Fresenius (future name: Grafalon)		RVG 17602	Fresenius Kabi Nederland Bv (Local MAH For Fresenius Biotech Gmbh)	Netherlands
Atg-Fresenius (future name: Grafalon)		3543485 \$ 3543584 \$ 3543782 \$ 3543881	Fresenius Medical Care Portugal, Sa (Local MAH For Fresenius Biotech Gmbh)	Portugal
Atg-Fresenius (future name: Grafalon)		59/0229/01 –S	Neovii Biotech Gmbh	Slovakia
Atg-Fresenius (future name: Grafalon)		14214	Neovii Biotech Gmbh	Sweden
Atg-Fresenius (future name: Grafalon)		UP/1-530-09/13-02/71	Hospitalija Trgovina D.O.O.	Croatia
Atg-Fresenius (future name: Grafalon)		PA 1015/001/001	Neovii Biotech Gmbh	Ireland
Atg-Fresenius S (future name: Grafalon)		452A/87	Neovii Biotech Gmbh	Germany
Globulines Antilymphocytaires Fresenius (future name: Grafalon)		34009 560 884 1 6 \$ 34009 560 885 8 4 \$ 34009 560 886 4 5 \$ 34009 560 887 0 6	Neovii Biotech Gmbh	France
Grafalon		BE 137873	Neovii Biotech Gmbh	Belgium

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Grafalon		59/256/97-C	Neovii Biotech Gmbh	Czech Republic
Grafalon		431004	Neovii Biotech Gmbh	Estonia
Grafalon	AT/H/0478/001/DC	042421014 \$ 042421026	Neovii Biotech Gmbh	Italy
Grafalon		7331	Neovii Biotech Gmbh	Poland
Grafalon		7711/2015/01-02	Neovii Biotech Gmbh	Romania
Grafalon		62.759	Neovii Biotech Gmbh	Spain
Grafalon 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung		2-00242	Neovii Biotech Gmbh	Austria
Grafalon SCT 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung	AT/H/0478/001/DC	235079	Neovii Biotech Gmbh	Austria