



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 December 2015
EMA/40805/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: human anti-d immunoglobulin

Procedure No.: PSUSA/00001614/201503



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
Rhesonativ	SE/H/0541/001	2-00386	Octapharma Pharmazeutika Produktionsgesmbh	Austria
Rhophylac	DE/H/0211/002	2-00331	Csl Behring Gmbh	Austria
Rhogam		BE001294 BE254886	Kedrion S.P.A.	Belgium
Rhophylac	DE/H/0211/001 DE/H/0211/002	BE260382 BE260391	Csl Behring Gmbh	Belgium
Rhesonativ	SE/H/0541/001	20060129	Octapharma (Ip)-Ltd.	Bulgaria
Rhesonativ		HR-H-584583753	Jana Pharm D.O.O.	Croatia
Rhesonativ	SE/H/0541/001	20158	Hi-Med Solutions (Cyprus) Ltd	Cyprus
Rhesonativ	SE/H/0541/001	59/134/06-C	Octapharma (Ip)-Ltd.	Czech Republic
Rhophylac	DE/H/0211/002	59/587/07-C	Csl Behring Gmbh	Czech Republic
Rhesonativ	SE/H/0541/001	38705	Octapharma Ab	Denmark
Rhophylac	DE/H/0211/001	34861	Csl Behring Gmbh	Denmark
Rhophylac	DE/H/0211/002	34862	Csl Behring Gmbh	Denmark
Rhesonativ	SE/H/0541/001	567407	Octapharma (Ip)-Ltd.	Estonia
Rhesonativ	SE/H/0541/001	23715	Octapharma Ab	Finland
Rhophylac	DE/H/0211/001 DE/H/0211/002	18132 18133	Csl Behring Gmbh	Finland
Rhesonativ	SE/H/0541/001	399 836-4 399 837-0 399 838-7	Octapharma France	France
Rhophylac	DE/H/0211/001	NL 28645	Csl Behring Gmbh	France
Rhophylac	DE/H/0211/002	NL 28646	Csl Behring Gmbh	France
Rhesonativ		PEI.H.03287.01.1	Octapharma Gmbh	Germany
Rhophylac	DE/H/0211/001 DE/H/0211/002	PEI.H.00399.02.1 PEI.H.00399.03.1	Csl Behring Gmbh	Germany
Rhophylac	DE/H/0211/002	53832/17-07-2009	Csl Behring Mepe	Greece

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Rhesonativ	SE/H/0541/001	OGYI-T-20152/01 OGYI-T-20152/02 OGYI-T-20152/03	Octapharma (Ip)-Ltd.	Hungary
Rhophylac	DE/H/0211/002	OGYI-T-20431/01	Csl Behring Gmbh	Hungary
Rhesonativ	SE/H/541/01	IS/1/07/052/01	Octapharma Ab	Iceland
Rhophylac	DE/H/0211/001	IS/1/03/021/01	Csl Behring Gmbh	Iceland
Rhophylac	DE/H/0211/002	IS/1/03/021/02	Csl Behring Gmbh	Iceland
Rhesonativ	SE/H/0541/001	PA 521/11/2	Octapharma-Ltd	Ireland
Rhophylac	DE/H/0211/002	PA 0800/006/002	Csl Behring Gmbh	Ireland
Immunorho		022547018 022547020	Kedrion S.P.A.	Italy
Immunorho		022547044	Kedrion S.P.A.	Italy
Rhophylac	DE/H/0211/001 DE/H/0211/002	036161014/M 036161026/M	Csl Behring Gmbh	Italy
Rhesonativ	SE/H/541/01	07-0329	Octapharma (Ip)-Ltd.	Latvia
Rhesonativ	SE/H/0541/001	LT/1/08/1082/001 LT/1/08/1082/002 LT/1/08/1082/003	Octapharma (Ip)-Ltd.	Lithuania
Rhesonativ	SE/H/0541/001	2006040004: 0430077 (1X1ML) 2006040004: 0430081 (1X2ML) 2006040004: 0430094 (10X2ML)	Octapharma Benelux S.A./N.V.	Luxembourg
Rhogam		1999095334	Kedrion Spa	Luxembourg
Rhophylac	DE/H/0211/001 DE/H/0211/002	1013/04010041 1013/04010042	Csl Behring Gmbh	Luxembourg
Rhesonativ	SE/H/0541/001	MA754/03001	Octapharma (Ip)-Ltd.	Malta
Rhesonativ	SE/H/0541/001	RVG 33233	Octapharma Benelux S.A./N.V.	Netherlands
Rhophylac	DE/H/0211/001 DE/H/0211/002	RVG 27449 RVG 27450	Csl Behring Gmbh	Netherlands

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Rhesonativ	SE/H/541/01	05-3798 (1ML, 2ML)	Octapharma A/S	Norway
Rhophylac	DE/H/0211/001	03-1762	Csl Behring Gmbh	Norway
Rhophylac	DE/H/0211/002	03-1765	Csl Behring Gmbh	Norway
Rhesonativ	SE/H/0541/001	14613	Octapharma (Ip)-Ltd.	Poland
Rhophylac	DE/H/0211/002	14312	Csl Behring Gmbh	Poland
Rhesonativ	SE/H/0541/001	5768387 5768486 5768585	Octapharma Produtos Farmaceuticos, Lda.	Portugal
Rhophylac	DE/H/0211/001 DE/H/0211/002	5026687 5026786	Csl Behring Gmbh	Portugal
Winrho 1500 LQ		5492012	Cangene Europe Limited	Portugal
Rhesonativ	SE/H/541/01	5338/2013/01-02-03	Octapharma (Ip)-Ltd.	Romania
Rhogam		4735/2004/01 4735/2004/02 4735/2004/03	Kedrion S.P.A.	Romania
Rhesonativ	SE/H/0541/001	59/0078/08-S	Octapharma (Ip)-Ltd.	Slovakia
Rhophylac	DE/H/0211/002	59/0397/07-S	Csl Behring Gmbh	Slovakia
Rhesonativ	SE/H/0541/001	5363-I-994/14 5363-I-995/14 5363-I-996/14	Octapharma (Ip)-Ltd.	Slovenia
Rhophylac	DE/H/0211/002	5363-I-144/12	Csl Behring Gmbh	Slovenia
Rhophylac	DE/H/0211/002	69.377	Csl Behring Gmbh	Spain
Rhesonativ	SE/H/0541/001	86972	Octapharma Ab	Sweden
Rhophylac	DE/H/0211/001 DE/H/0211/002	18141 18142	Csl Behring Gmbh	Sweden
D-Gam		PL 08801/0047 PL 08801/0048 PL 08801/0049	Bio Products Laboratory	United Kingdom
Rhophylac	DE/H/0211/002	PL 15036/0019	Csl Behring Gmbh	United Kingdom

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Rhesonativ	SE/H/0541/001	1800/2010	Octapharma Italy S.P.A.	Italy
Immunorho		AA128/00501	Kedrion SPA	Malta