



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 November 2018  
EMA/827769/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: human anti-d immunoglobulin

Procedure no.: PSUSA/00001614/201803

---

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

An agency of the European Union



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
Rhophylac 300 micrograme/2 ml soluție injectabilă în seringă preumplută	DE/H/0211/002	5031/2012/01	CSL BEHRING GMBH	RO
RHOPHYLAC 300 microgrammes/2 ml, solution injectable en seringue préremplie	DE/H/0211/002	363970-2	CSL BEHRING GMBH	FR
Rhophylac 300 microgrammi/2 ml, soluzione iniettabile in siringa pre-riempita	DE/H/0211/002	036161026/M	CSL BEHRING GMBH	IT
Rhophylac 300 mikrogramov/2 ml raztopina za injiciranje v napolnjeni injekcijski brizgi	DE/H/0211/002	H/08/01347/001-002	CSL BEHRING GMBH	SI
Rhophylac 1500 IU, injektioneste, liuos esitäytetyssä ruiskussa	DE/H/0211/002	18133	CSL BEHRING GMBH	FI
Rhophylac 1500 IU / 2 ml injeksjonsvæske, oppløsning, i ferdigfylt sprøyte	DE/H/0211/002	03-1765	CSL BEHRING GMBH	NO
Rhophylac 300 mikrogramów / 2 ml, roztwór do wstrzykiwań w ampułko-strzykawce	DE/H/0211/002	14312	CSL BEHRING GMBH	PL
Rhophylac 300 Mikrogramm / 2 ml Injektionslösung in einer Fertigspritze	DE/H/0211/002	2-00331	CSL BEHRING GMBH	AT
Rhophylac 300 microgrammes, 2ml solution injectable dans une seringue pré-remplie	DE/H/0211/002	BE260391	CSL BEHRING GMBH	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
Rhophylac 300 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/002	BE260391	CSL BEHRING GMBH	BE
Rhophylac 300 mikrogramů/2 ml, injekční roztok v předplněné injekční stříkačce	DE/H/0211/002	59/587/07-C	CSL BEHRING GMBH	CZ
Rhophylac® 300 Mikrogramm / 2 ml, Injektionslösung in Fertigspritze	DE/H/0211/002	PEI.H.00399.02.1	CSL BEHRING GMBH	DE
Rhophylac	DE/H/0211/002	34862	CSL BEHRING GMBH	DK
Rhophylac 300 microgramos, 2 mL de solución inyectable en jeringa precargada	DE/H/0211/002	69.377	CSL BEHRING GMBH	ES
Rhophylac 300 micrograms / 2 ml solution for injection in pre-filled syringe	DE/H/0211/002	PL 15036/0019	CSL BEHRING GMBH	UK
Rhophylac 300 μικρογραμμάρια/2ml, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα	DE/H/0211/002	53832/17-07-2009	CSL BEHRING MEPE	GR
Rhophylac 300 mikrogramm / 2 ml, oldatos injekció előretöltött fecskendőben	DE/H/0211/002	OGYI-T-20431/01	CSL BEHRING GMBH	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
Rhophylac 300 micrograms / 2 ml, solution for injection in pre-filled syringe	DE/H/0211/002	PA 800/6/2	CSL BEHRING GMBH	IE
Rhophylac 300 míkrogrömm/2 ml stungulyf, lausn í áfylltri sprautu	DE/H/0211/002	IS/1/03/021/02	CSL BEHRING GMBH	IS
Rhophylac 300 microgrammes, 2ml solution injectable dans une seringue pré-remplie	DE/H/0211/002	1013/04010041	CSL BEHRING GMBH	LU
Rhophylac 300 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/002	1013/04010041	CSL BEHRING GMBH	LU
Rhophylac 300 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/002	RVG 27450	CSL BEHRING GMBH	NL
Rhophylac 300 microgramas / 2 ml solução injectável em seringa pré-cheia	DE/H/0211/002	5026786	CSL BEHRING GMBH	PT
Rhophylac 1500 IE (300 µg), injektionsvätska, lösning, förfylld spruta	DE/H/0211/002	18142	CSL BEHRING GMBH	SE
Rhophylac 300 mikrogramov/2 ml injekčný roztok naplnený v injekčnej striekačke	DE/H/0211/002	59/0397/07-S	CSL BEHRING GMBH	SK
Rhophylac 300 μικρογραμμάρια/2ml, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα	DE/H/0211/002	022756	CSL BEHRING GMBH	CY

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
RhoGAM Ultra-Filtered PLUS 50 microgram oplossing voor injectie	not available	BE254886	KEDRION S.P.A.	BE
RhoGAM Ultra-Filtered PLUS 300 microgram oplossing voor injectie	not available	BE001294	KEDRION S.P.A.	BE
RhoGAM Ultra-Filtered PLUS 300 micrograme soluție injectabilă	not available	9547/2016/01-02-03	KEDRION S.P.A.	RO
RHO GAM ULTRA-FILTERED KEDRION SPA 1500 UI/1 ML SOLUTION INJECTABLE	not available	1999095334	KEDRION S.P.A.	LU
IMMUNORHO 200 microgrammi (1000 UI) Polvere e solvente per soluzione iniettabile per uso intramuscolare	not available	022547020	KEDRION S.P.A.	IT
IMMUNORHO 300 microgrammi (1500 UI) Polvere e solvente per soluzione iniettabile per uso intramuscolare	not available	022547018	KEDRION S.P.A.	IT
IMMUNORHO 300 microgrammi (1500 UI) Soluzione iniettabile per uso intramuscolare	not available	022547044	KEDRION S.P.A.	IT
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	2006040004: 0430081 (1X2ML)	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	2006040004: 0430094 (10X2ML)	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	399838-7 OU 3400939983875 (10X2)	OCTAPHARMA FRANCE	FR
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	399837-0 OU 3400939983707 (1X2)	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
Rhesonativ 625 NE/ml oldatos injekció	SE/H/0541/001	OGYI-T-20152/03 (10X2ML)	OCTAPHARMA (IP) LTD.	HU
Rhesonativ 625 NE/ml oldatos injekció	SE/H/0541/001	OGYI-T-20152/02 (1X2ML)	OCTAPHARMA (IP) LTD.	HU
Rhesonativ 625 UI/ml, soluzione iniettabile	SE/H/0541/001	039596022 (2ML)	OCTAPHARMA ITALY S.P.A.	IT
Rhesonativ 625 UI/ml, soluzione iniettabile	SE/H/0541/001	039596034 (10X 2ML)	OCTAPHARMA ITALY S.P.A.	IT
Rhesonativ 625 TV/ml injekcinis tirpalas	SE/H/0541/001	LT/1/08/1082/002 (2ML)	OCTAPHARMA (IP) LTD.	LT
Rhesonativ 625 TV/ml injekcinis tirpalas	SE/H/0541/001	LT/1/08/1082/003 (10X2ML)	OCTAPHARMA (IP) LTD.	LT
Rhesonativ 625 UI/ml, solução injetável	SE/H/0541/001	5768585 (10X2ML)	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 625 UI/ml, solução injetável	SE/H/0541/001	5768486 (1X2ML)	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 625 SV/ml □ķīdums injekcijām	SE/H/0541/001	07-0329	OCTAPHARMA (IP) LTD.	LV
Rhesonativ 625 I.E./ml Injektionslösung	SE/H/0541/001	2-00386	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
Rhesonativ 625 IU/ml, solution for injection	SE/H/0541/001	20060129	OCTAPHARMA (IP) LTD.	BG
Rhesonativ 625 IU/ml, διάλυμα για ένεση	SE/H/0541/001	20158	HI-MED SOLUTIONS (CYPRUS) LTD	CY
Rhesonativ 625 IU/ml, injekční roztok	SE/H/0541/001	59/134/06-C	OCTAPHARMA (IP) SPRL	CZ
Rhesonativ, Injectionsvæske, opløsning	SE/H/0541/001	38705	OCTAPHARMA AB	DK
Rhesonativ, 625 RÜ/ml, süstelahus	SE/H/0541/001	567407	OCTAPHARMA (IP) SPRL	EE
Rhesonativ 625 IU/ml, injektioneste, liuos	SE/H/0541/001	23715	OCTAPHARMA AB	FI

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 625 UI/ml, solution injectable	SE/H/0541/001	399836-4 OU 3400939983646 (1X1)	OCTAPHARMA FRANCE	FR
Rhesonativ 625 NE/ml oldatos injekció	SE/H/0541/001	OGYI-T-20152/01 (1X1ML)	OCTAPHARMA (IP) LTD.	HU
Rhesonativ 625 IU/ml injekčný roztok	SE/H/0541/001	59/0078/08-S	OCTAPHARMA (IP) LTD.	SK
Rhesonativ 625 a.e./ml, stungulyf, lausn	SE/H/0541/001	IS/1/07/052/01	OCTAPHARMA AB	IS
Rhesonativ 625 UI/ml, soluzione iniettabile	SE/H/0541/001	039596010 (1ML)	OCTAPHARMA ITALY S.P.A.	IT
Rhesonativ 625 TV/ml injekcinis tirpalas	SE/H/0541/001	LT/1/08/1082/001 (1ML)	OCTAPHARMA (IP) LTD.	LT
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	2006040004: 0430077 (1X1ML)	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 625 IU/ml, solution for injection	SE/H/0541/001	MA754/03001	OCTAPHARMA (IP) LTD.	MT
Rhesonativ 625 IE/ml, oplossing voor injectie	SE/H/0541/001	RVG 33233	OCTAPHARMA GMBH	NL
Rhesonativ 625 IE/ml injeksjonsvæske, oppløsning	SE/H/0541/001	05-3798 (1ML, 2ML)	OCTAPHARMA AS	NO
Rhesonativ, 625 j.m./ml, roztwór do wstrzykiwań	SE/H/0541/001	14613	OCTAPHARMA (IP) LTD.	PL
Rhesonativ 625 UI/ml, solução injetável	SE/H/0541/001	5768387 (1X1ML)	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 625 UI/ml solutie injectabila	SE/H/0541/001	5338/2013/01	OCTAPHARMA (IP) LTD.	RO
Rhesonativ 300 Mikrogramm in 2 ml i.m. Injektionslösung	not available	PEI.H.03287.01.1	OCTAPHARMA GMBH	DE
Rhesonativ 625 IE/ml injektionsvätska, lösning	SE/H/0541/001	86972	OCTAPHARMA AB	SE
Rhesonativ 625 UI/ml solutie injectabila	SE/H/0541/001	5338/2013/02	OCTAPHARMA (IP) LTD.	RO

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 625 UI/ml solutie injectabila	SE/H/0541/001	5338/2013/03 (10X2ML)	OCTAPHARMA (IP) LTD.	RO
Rhesonativ 625 i.e./ml raztopina za injiciranje	SE/H/0541/001	H/06/01346/002	OCTAPHARMA (IP) LTD.	SI
Rhesonativ 625 i.e./ml raztopina za injiciranje	SE/H/0541/001	H/06/01346/001	OCTAPHARMA (IP) LTD.	SI
Rhesonativ 625 i.e./ml raztopina za injiciranje	SE/H/0541/001	H/06/01346/003	OCTAPHARMA (IP) LTD.	SI
Rhesonativ 750 IE/ml injektionsvätska, lösning	SE/H/541/002/DC	55273	OCTAPHARMA AB	SE
Rhesonativ 750 i.e./ml raztopina za injiciranje	SE/H/0541/002/DC	H/06/01346/004	OCTAPHARMA (IP) LTD.	SI
Rhesonativ 750 i.e./ml raztopina za injiciranje	SE/H/0541/002/DC	H/06/01346/005	OCTAPHARMA (IP) LTD.	SI
Rhesonativ 750 i.e./ml raztopina za injiciranje	SE/H/0541/002/DC	H/06/01346/006	OCTAPHARMA (IP) LTD.	SI
Rhesonativ 750 NE/ml oldatos injekció	SE/H/541/002/DC	OGYI-T-20152/04	OCTAPHARMA (IP) LTD.	HU
Rhesonativ, 750 j.m./ml, roztwór do wstrzykiwań	SE/H/541/002/DC	24406	OCTAPHARMA (IP) LTD.	PL
Rhesonativ 750 UI/ml, solução injetável	SE/H/0541/002/DC	5731757	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 750 IU/ml injekčný roztok	SE/H/0541/002	59/0055/18-S	OCTAPHARMA (IP) LTD.	SK
Rhesonativ 750 IU/ml, solution for injection	SE/H/541/002/DC	20180094	OCTAPHARMA (IP) LTD.	BG
Rhesonativ 750 UI/ml solutie injectabila	SE/H/0541/002	10306/2017/03	OCTAPHARMA (IP) LTD.	RO
Rhesonativ 625 IU/ml, solution for injection	SE/H/0541/001	PA2219/003/001	OCTAPHARMA (IP) SPRL	IE
Rhesonativ 300 Mikrogramm in 2 ml i.m. Injektionslösung	not available	2018060130: 0854442 (1 X 2ML)	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
Rhesonativ 300 Mikrogramm in 2 ml i.m. Injektionslösung	not available	2018060130: 0846034 (5 X 2ML)	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 750 UI/ml, solutie injectabila	SE/H/0541/002	10306/2017/01	OCTAPHARMA (IP) LTD.	RO
Rhesonativ 750 UI/ml, solutie injectabila	SE/H/0541/002	10306/2017/02	OCTAPHARMA (IP) LTD.	RO
Rhesonativ 300 Mikrogramm in 2 ml i.m. Injektionslösung	not available	PEI.H.03287.01.1	OCTAPHARMA GMBH	DE
RHOPHYLAC 200 microgrammes/2 ml, solution injectable en seringue préremplie	DE/H/0211/001	363970-2	CSL BEHRING GMBH	FR
Rhophylac 200 microgrammi/2 ml, soluzione iniettabile in siringa pre-riempita	DE/H/0211/001	036161014/M	CSL BEHRING GMBH	IT
Rhophylac 1000 IU, injektioneste, liuos esitäytetyssä ruiskussa	DE/H/0211/001	18132	CSL BEHRING GMBH	FI
Rhophylac 1000 IU / 2 ml injeksjonsvæske, oppløsning, i ferdigfylt sprøyte	DE/H/0211/001	03-1762	CSL BEHRING GMBH	NO
Rhophylac 200 microgrammes / 2ml, solution injectable dans une seringue pré-remplie	DE/H/0211/001	BE260382	CSL BEHRING GMBH	BE
Rhophylac 200 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/001	BE260382	CSL BEHRING GMBH	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
Rhophylac® 200 Mikrogramm / 2 ml, Injektionslösung in Fertigspritze	DE/H/0211/001	PEI.H.00399.03.1	CSL BEHRING GMBH	DE
Rhophylac, injektionsvæske, opløsning, fyldt injektionssprøjte	DE/H/0211/001	34861	CSL BEHRING GMBH	DK
Rhophylac 200 míkrogrömm/2 ml stungulyf, lausn í áfylltri sprautu	DE/H/0211/001	IS/1/03/021/01	CSL BEHRING GMBH	IS
Rhophylac 200 microgrammes, 2ml solution injectable dans une seringue pré-remplie	DE/H/0211/001	1013/04010042	CSL BEHRING GMBH	LU
Rhophylac 200 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/001	1013/04010042	CSL BEHRING GMBH	LU
Rhophylac 200 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/001	RVG 27449	CSL BEHRING GMBH	NL
Rhophylac 200 microgramas / 2 ml solução injetável em seringa pré-cheia	DE/H/0211/001	5026687	CSL BEHRING GMBH	PT
Rhophylac 1000 IE (200 µg), injektionsvätska, lösning, förfylld spruta	DE/H/0211/001	18141	CSL BEHRING GMBH	SE
Rhesonativ 625 IU/ml otopina za injekciju	not available	HR-H-584583753	JANA PHARM D.O.O.	HR

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
D-GAM ®, Human Anti-D Immunoglobulin, 250 IU, solution for injection.	not available	19578	BIO PRODUCTS LABORATORY	CY
D-GAM ®, Human Anti-D Immunoglobulin, 500 IU, solution for injection.	not available	MA049/00801	BIO PRODUCTS LABORATORY	MT
D-GAM ®, Human Anti-D Immunoglobulin, 500 IU, solution for injection.	not available	PL 08801/0048	BIO PRODUCTS LABORATORY	UK
D-GAM ®, Human Anti-D Immunoglobulin, 1,500 and 2,500 IU, solution for injection.	not available	PL 08801/0049	BIO PRODUCTS LABORATORY	UK