



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2024
EMA/480206/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): human anti-d immunoglobulin

Procedure No. PSUSA/00001614/202403



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 Mikrogramm / 2 ml Injektionslösung in einer Fertigspritze	DE/H/0211/002	2-00331	CSL BEHRING GMBH	AT
Rhesonativ 625 I.E./ml Injektionslösung	SE/H/0541/001	2-00386	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
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
Rhophylac 300 microgrammes / 2ml, solution injectable dans une seringue pré-remplie	DE/H/0211/002	BE260391	CSL BEHRING GMBH	BE
Rhophylac 300 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/002	BE260391	CSL BEHRING GMBH	BE
Rhophylac® 300 Mikrogramm / 2 ml Injektionslösung in Fertigspritze	DE/H/0211/002	BE260391	CSL BEHRING GMBH	BE
Rhophylac 200 microgrammes / 2ml, solution injectable dans une seringue pré-remplie	DE_RHOPHYLAC_200 MG/2 ML_SOLUTION FOR INJECTION	BE260382	CSL BEHRING GMBH	BE
Rhophylac 200 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE_RHOPHYLAC_200 MG/2 ML_SOLUTION FOR INJECTION	BE260382	CSL BEHRING GMBH	BE

Rhophylac® 200 Mikrogramm / 2 ml Injektionslösung in Fertigspritze	DE_RHOPHYLAC_200 MG/2 ML_SOLUTION FOR INJECTION	BE260382	CSL BEHRING GMBH	BE
Rhesonativ 625 IU/ml, solution for injection	SE/H/0541/001	20060129	OCTAPHARMA (IP) SPRL	BG
Rhesonativ 750 IU/ml, solution for injection	SE/H/0541/002	20180094	OCTAPHARMA (IP) SPRL	BG
Rhophylac 300 μκρογραμμάρια/2ml, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα	DE/H/0211/002	022756	CSL BEHRING GMBH	CY
Rhesonativ 625 IU/ml, διάλυμα για ένεση	SE/H/0541/001	20158	OCTAPHARMA (IP) SPRL	CY
D-GAM®, Human Anti- D Immunoglobulin, 250 IU, solution for injection.	not available	19578	BPL BIOPRODUCTS LABORATORY GMBH	CY
Rhophylac 300 mikrogramů/2 ml injekční roztok v předplněné injekční stříkačce	DE/H/0211/002	59/587/07-C	CSL BEHRING GMBH	CZ
Rhesonativ 625 IU/ml, injekční roztok	SE/H/0541/001	59/134/06-C	OCTAPHARMA (IP) SPRL	CZ
Rhophylac® 300 Mikrogramm / 2 ml, Injektionslösung in Fertigspritze	DE/H/0211/002	PEI.H.00399.02.1	CSL BEHRING GMBH	DE
Rhophylac® 200 Mikrogramm / 2 ml, Injektionslösung in Fertigspritze	DE/H/0211/001	PEI.H.00399.03.1	CSL BEHRING GMBH	DE
Rhesonativ 300 Mikrogramm in 2 ml i.m. Injektionslösung.	not available	PEI.H.03287.01.1	OCTAPHARMA GMBH	DE
Rhesonativ, Injectionsvæske, opløsning	SE/H/0541/001	38705	OCTAPHARMA AB	DK
Rhophylac, injektionsvæske, opløsning i fyldt injektionssprøjte	DE/H/0211/002	34862	CSL BEHRING GMBH	DK

Rhesonativ, 625 RÜ/ml, süstelahus	SE/H/0541/001	567407	OCTAPHARMA (IP) SPRL	EE
Rhophylac 300 microgramos/2 ml de solución inyectable en jeringa precargada.	DE/H/0211/002	69.377	CSL BEHRING GMBH	ES
Rhesonativ 625 IU/ml, injektioneste, liuos	SE/H/0541/001	23715	OCTAPHARMA AB	FI
RHOPHYLAC 300 microgrammes/2 ml, solution injectable en seringue préremplie	DE/H/0211/002	363 971-9	CSL BEHRING GMBH	FR
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	399838-7 OU 3400939983875	OCTAPHARMA FRANCE	FR
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	399837-0 OU 3400939983707	OCTAPHARMA FRANCE	FR
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	399836-4 OU 3400939983646	OCTAPHARMA FRANCE	FR
RHOPHYLAC 200 microgrammes/2 ml, solution injectable en seringue préremplie	DE/H/0211/001	363 970-2	CSL BEHRING GMBH	FR
Rhophylac 300 μικρογραμμάριο/2ml, ενέσιμο διάλυμα σε προγεμισμένη σύριγγα	DE_RHOPHYLAC_300 MG/2 ML_SOLUTION FOR INJECTION	3212/16-01-2008	CSL BEHRING GMBH	GR
Rhesonativ 625 IU/ml otopina za injekciju	not available	HR-H-584583753	JANA PHARM D.O.O.	HR
Rhophylac 300 mikrogramm /2 ml oldatos injekció előretöltött fecskendőben	DE/H/0211/002	OGYI-T-20431/01	CSL BEHRING GMBH	HU
Rhesonativ 625 NE/ml oldatos injekció	SE/H/0541/001	OGYI-T-20152/03	OCTAPHARMA (IP) SPRL	HU
Rhesonativ 625 NE/ml oldatos injekció	SE/H/0541/001	OGYI-T-20152/02	OCTAPHARMA (IP) SPRL	HU
Rhesonativ 625 NE/ml oldatos injekció	SE/H/0541/001	OGYI-T-20152/01	OCTAPHARMA (IP) SPRL	HU
Rhesonativ 750 NE/ml oldatos injekció	SE/H/541/002	OGYI-T-20152/04	OCTAPHARMA (IP) SPRL	HU

Rhophylac 300 micrograms / 2 ml, solution for injection in pre-filled syringe	DE_RHOPHYLAC_300 MG/2 ML_SOLUTION FOR INJECTION	PA 800/6/2	CSL BEHRING GMBH	IE
Rhophylac 300 míkrógrömm/2 ml stungulyf, lausn í áfylltri sprautu	DE/H/0211/002	IS/1/03/021/02	CSL BEHRING GMBH	IS
Rhesonativ 625 a.e./ml, stungulyf, lausn	SE/H/0541/001	IS/1/07/052/01	OCTAPHARMA AB	IS
Rhophylac 200 míkrógrömm/2 ml stungulyf, lausn í áfylltri sprautu	DE/H/0211/001	IS/1/03/021/01	CSL BEHRING GMBH	IS
IMMUNORHO 300 microgrammi (1500 UI) Soluzione iniettabile per uso intramuscolare	not available	022547044	KEDRION S.P.A.	IT
Rhophylac 300 microgrammi/2 ml, soluzione iniettabile in siringa pre-riempita	DE/H/0211/002	036161026	CSL BEHRING GMBH	IT
Rhesonativ 625 UI/ml, soluzione iniettabile	SE/H/0541/001	039596022	OCTAPHARMA ITALY S.P.A.	IT
Rhesonativ 625 UI/ml, soluzione iniettabile	SE/H/0541/001	039596034	OCTAPHARMA ITALY S.P.A.	IT
Rhesonativ 625 UI/ml, soluzione iniettabile	SE/H/0541/001	039596010	OCTAPHARMA ITALY S.P.A.	IT
Rhophylac 200 microgrammi/2 ml, soluzione iniettabile in siringa pre-riempita	DE/H/0211/001	036161014	CSL BEHRING GMBH	IT
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

Rhesonativ 625 TV/ml injekcinis tirpalas	SE/H/0541/001	LT/1/08/1082/002	OCTAPHARMA (IP) SPRL	LT
Rhesonativ 625 TV/ml injekcinis tirpalas	SE/H/0541/001	LT/1/08/1082/003	OCTAPHARMA (IP) SPRL	LT
Rhesonativ 625 TV/ml injekcinis tirpalas	SE/H/0541/001	LT/1/08/1082/001	OCTAPHARMA (IP) SPRL	LT
RHOGAM ULTRA- FILTERED KEDRION SPA 1500 UI/ 1 mL Solution injectable	not available	1999095334	KEDRION S.P.A.	LU
Rhophylac 300 microgrammes / 2ml, solution injectable dans une seringue pré-remplie	DE/H/0211/002	2004010041	CSL BEHRING GMBH	LU
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	2006040004: 0430081	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	2006040004: 0430094	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 625 UI/ml, solution injectable	SE/H/0541/001	2006040004: 0430077	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ 300 Mikrogramm in 2 ml i.m. Injektionslösung	not available	2018060130: 0854442	OCTAPHARMA BENELUX S.A.	LU
Rhesonativ300 Mikrogramm in 2 ml i.m. Injektionslösung	not available	2018060130: 0846034	OCTAPHARMA BENELUX S.A.	LU
Rhophylac 200 microgrammes / 2ml, solution injectable dans une seringue pré-remplie	DE/H/0211/001	2004010042	CSL BEHRING GMBH	LU
Rhesonativ 625 SV/ml šķīdums injekcijām	SE/H/0541/001	07-0329	OCTAPHARMA (IP) SPRL	LV
Rhophylac 300 micrograms / 2 ml solution for injection in pre-filled syringe	DE/H/0211/002	MA 665/00601	CSL BEHRING GMBH	MT
Rhesonativ 625 IU/ml, solution for injection	SE/H/0541/001	MA1219/01001	OCTAPHARMA (IP) SPRL	MT
Rhesonativ 625 IU/ml, solution for injection	SE/H/0541/001	MA1219/01002	OCTAPHARMA (IP) SPRL	MT

Rhophylac 300 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/002	RVG 27450	CSL BEHRING GMBH	NL
Rhesonativ 625 IE/ml, oplossing voor injectie	SE/H/0541/001	RVG 33233	OCTAPHARMA GMBH	NL
Rhophylac 200 microgram / 2 ml, oplossing voor injectie in een voorgevulde spuit	DE/H/0211/001	RVG 27449	CSL BEHRING GMBH	NL
Rhesonativ 625 IE/ml injeksjonsvæske, oppløsning	SE/H/0541/001	05-3798	OCTAPHARMA AS	NO
Rhophylac 300, 300 mikrogramów / 2 ml, roztwór do wstrzykiwań w ampulko-strzykawce	DE/H/0211/002	14312	CSL BEHRING GMBH	PL
Rhesonativ, 625 j.m./ml, roztwór do wstrzykiwań	SE/H/0541/001	14613	OCTAPHARMA (IP) SPRL	PL
Rhesonativ, 750 j.m./ml, roztwór do wstrzykiwań	SE/H/0541/002	24406	OCTAPHARMA (IP) SPRL	PL
Rhophylac 300 microgramas / 2 ml solução injetável em seringa pré-cheia	DE/H/0211/002	5026786	CSL BEHRING GMBH	PT
Rhesonativ 625 UI/ml, solução injetável	SE/H/0541/001	5768585	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 625 UI/ml, solução injetável	SE/H/0541/001	5768486	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 625 UI/ml, solução injetável	SE/H/0541/001	5768387	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhesonativ 750 UI/ml, solução injetável	SE/H/0541/002	5731757	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Rhophylac 200 microgramas / 2 ml solução injetável em seringa pré-cheia	DE/H/0211/001	5026687	CSL BEHRING GMBH	PT
RhoGAM Ultra-Filtered PLUS 300 micrograme soluție injectabilă	not available	9547/2016/01	KEDRION S.P.A.	RO

RhoGAM Ultra-Filtered PLUS 300 micrograme soluție injectabilă	not available	9547/2016/02	KEDRION S.P.A.	RO
RhoGAM Ultra-Filtered PLUS 300 micrograme soluție injectabilă	not available	9547/2016/03	KEDRION S.P.A.	RO
Rhophylac 300 micrograme/2 ml soluție injectabilă în seringă preumplută	DE/H/0211/002	9966/2017/01	CSL BEHRING GMBH	RO
Rhesonativ 625 UI/ml soluție injectabilă	SE/H/0541/001	5338/2013/01	OCTAPHARMA (IP) SPRL	RO
Rhesonativ 625 UI/ml soluție injectabilă	SE/H/0541/001	5338/2013/02	OCTAPHARMA (IP) SPRL	RO
Rhesonativ 625 UI/ml soluție injectabilă	SE/H/0541/001	5338/2013/03	OCTAPHARMA (IP) SPRL	RO
Rhesonativ 750 UI/ml soluție injectabilă	SE/H/0541/002	14524/2022/03	OCTAPHARMA (IP) SPRL	RO
Rhesonativ 750 UI/ml, soluție injectabilă	SE/H/0541/002	14524/2022/01	OCTAPHARMA (IP) SPRL	RO
Rhesonativ 750 UI/ml, soluție injectabilă	SE/H/0541/002	14524/2022/02	OCTAPHARMA (IP) SPRL	RO
Rhesonativ 625 IE/ml injektionsvätska, lösning	SE/H/0541/001	86972	OCTAPHARMA AB	SE
Rhesonativ 750 IE/ml injektionsvätska, lösning	SE/H/0541/002	55273	OCTAPHARMA AB	SE
Rhophylac 300 mikrogramov/2 ml raztopina za injiciranje v napolnjeni injekcijski brizgi	DE/H/0211/002	H/08/01347/001	CSL BEHRING GMBH	SI
Rhophylac 300 mikrogramov/2 ml raztopina za injiciranje v napolnjeni injekcijski brizgi	DE/H/0211/002	H/08/01347/002	CSL BEHRING GMBH	SI
Rhesonativ 625 i.e./ml raztopina za injiciranje	SE/H/0541/001	H/06/01346/002	OCTAPHARMA (IP) SPRL	SI
Rhesonativ 625 i.e./ml raztopina za injiciranje	SE/H/0541/001	H/06/01346/001	OCTAPHARMA (IP) SPRL	SI

Rhesonativ 625 i.e./ml raztopina za injiciranje	SE/H/0541/001	H/06/01346/003	OCTAPHARMA (IP) SPRL	SI
Rhesonativ 750 i.e./ml raztopina za injiciranje	SE/H/0541/002	H/06/01346/004	OCTAPHARMA (IP) SPRL	SI
Rhesonativ 750 i.e./ml raztopina za injiciranje	SE/H/0541/002	H/06/01346/005	OCTAPHARMA (IP) SPRL	SI
Rhesonativ 750 i.e./ml raztopina za injiciranje	SE/H/0541/002	H/06/01346/006	OCTAPHARMA (IP) SPRL	SI
Rhophylac 300 mikrogramov/2 ml injektný roztok naplnený v injekcnej striekacke	DE/H/0211/002	59/0397/07-S	CSL BEHRING GMBH	SK
Rhesonativ 625 IU/ml injektný roztok	SE/H/0541/001	59/0078/08-S	OCTAPHARMA (IP) SPRL	SK
Rhesonativ 750 IU/ml injektný roztok	SE/H/0541/002	59/0055/18-S	OCTAPHARMA (IP) SPRL	SK
D-Gam 50 micrograms/ml solution for injection.	not available	PL 08801/0048	BIO PRODUCTS LABORATORY	XI
D-Gam 250 micrograms/ml solution for injection.	not available	PL 08801/0049	BIO PRODUCTS LABORATORY	XI
Rhophylac 300 micrograms / 2 ml solution for injection in pre-filled syringe	DE/H/0211/002	PL 15036/0019	CSL BEHRING GMBH	XI