



Human Rho(D) immune globulin

Targets (1)

IDENTIFICATION

Name

Human Rho(D) immune globulin

Accession Number

DB11597

Type

Biotech

Groups

Approved, Investigational

Biologic Classification

Protein Based Therapies
Polyclonal antibody (pAb)

Description

Human Rho(D) immune globulin is a medicine given by intramuscular or intravenous injection that is used to prevent the immunological condition known as Rh disease (or hemolytic disease of newborn). Rho (D) immune globulin is available as a sterile, lyophilized or liquid gamma globulin (IgG) fraction containing antibodies to the Rh0 (D) antigen (D antigen) under the name Rhophylac (IM/IV). Immune globulin was purified via ion-exchange chromatography method and prepared from pools of human plasma, where the donors are Rho (D)-negative donors who have been immunized with Rho(D)-positive RBCs. It was approved by FDA as treatment for suppression of rhesus (Rh) isoimmunization or chronic immune thrombocytopenic purpura (ITP) in adults.

Protein chemical formula

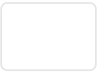
Not Available

Protein average weight

Not Available

Sequences

Not Available



Anti-D Immunoglobulins

Human anti-D immunoglobulin

IGG, Rho (D)

Immunoglobulin human anti-RH

Rh0(D) Immune Globulin Intravenous (Human)

Rho (D) immune globulin,human

Rho D immune globulin human

Rho(D) immune globulin (human)

Rho(D) immune globulin human

Rho(D) immune globulin IM human

Prescription Products

Search

NAME	DOSAGE	STRENGTH	ROUTE	LABELLER	MARKETING START	MARKETING END			
Hyp Rho D Inj 16.5%	Liquid	16.5 %	Intramuscular	Cutter Med & Biol, Division Of Miles Canada Ltd.	1979-12-31	Not applicable			
Hyperrho S/d Full Dose	Solution	1500 [iU]/1	Intramuscular	Grifols	1996-08-14	Not applicable			
Hyperrho S/d Mini-dose	Solution	250 [iU]/1	Intramuscular	Grifols	1996-08-14	Not applicable			
MICRhoGAM Ultra-Filtered PLUS	Injection, solution	50 ug/1	Intramuscular	Kedrion Melville Inc.	2007-03-09	Not applicable			
RhoGAM Ultra-Filtered PLUS	Injection, solution	300 ug/1	Intramuscular	Kedrion Melville Inc.	2007-03-09	Not applicable			
Rhophylac	Solution	1500 [iU]/2mL	Intramuscular; Intravenous	Csl Behring Ag	2009-01-06	Not applicable			
Winrho Sdf	Solution	15000 unit	Intramuscular; Intravenous	Saol Therapeutics Research Limited	Not applicable	Not applicable			



				Limited				
Winrho Sdf	Kit	1500 unit	Intramuscular; Intravenous	Aptevo Biotherapeutics Llc	1996-08-28	Not applicable		
Winrho Sdf	Solution	1500 unit	Intramuscular; Intravenous	Saol Therapeutics Research Limited	2008-06-16	Not applicable		

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Mixture Products

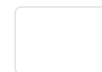
Search

NAME ↕	INGREDIENTS	DOSAGE ↕	ROUTE ↕	LABELLER ↕	MARKETING START ↕	MARKETING END ↕	↕	↕	↕
Winrho Sd Kit Inj	Human Rho(D) immune globulin (120 mcg) + Sodium Chloride (0.9 %)	Kit	Intramuscular; Intravenous	Rh Pharmaceuticals Inc.	1993-12-31	Not applicable			
Winrho Sd Kit Inj.	Human Rho(D) immune globulin (300 mcg) + Sodium Chloride (.9 %)	Kit	Intramuscular; Intravenous	Rh Pharmaceuticals Inc.	1993-12-31	Not applicable			

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Categories[Human Immunoglobulin G](#)[Serum](#)**UNII**[48W7181FLP](#)**CAS number**<https://www.drugbank.ca/drugs/DB11597>



Indication

Indicated for suppression of rhesus (Rh) isoimmunization in nonsensitized Rho (D)-negative women with an Rh-incompatible pregnancy, or in Rho (D)-negative individuals transfused with Rh0(D)-positive red blood cells (RBCs) or blood components containing Rh0(D)-positive RBCs. Also indicated in Rh0(D)-positive, non-splenectomized adult patients with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Associated Conditions

[Chronic Immune thrombocytopenic purpura](#)

Associated Therapies

[Prophylaxis of Rhesus isoimmunization](#)

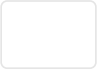
Pharmacodynamics

15000 international unit (IU) contains sufficient anti-Rho (D) to effectively suppress the immunizing potential of approximately 17mL of Rho (D) (D-positive) red blood cells [12]. Human Rho(D) immune globulin therapy prevents immunization to Rho (D)-positive red blood cells (RBC) by inducing antibody-mediated immunosuppression (AMIS) effectively clearing Rho-positive RBCs by rapidly binding to them. This prevents Rho-negative mothers to produce alloantibodies to paternally inherited RhD antigen expressed on fetal erythrocytes and cause haemolytic diseases of the newborn. Rho immune globulin increase platelet counts and reduce bleeding in Rho-positive patients with ITP by inhibiting autoantibody-mediated platelet clearance.

Mechanism of action

The mechanism of action of Rho(D) immune globulin therapy is unclear. It is suggested that Rho immune globulin predominantly prevents the antibody response during incompatible pregnancy by accelerating the phagocytosis of RBC's and clearance from the circulation before the recognition by the immune system. IgG-opsonized RBCs may interact with activating IgG receptors (FcγRs) on effector cells and elicit phagocytosis via mononuclear phagocytic system, primarily by macrophages. IgG may also stimulate complement activation on the RBC surface, followed by RBC lysis or complement receptor-mediated phagocytosis but to smaller extent [4]. Rho-specific IgG may inhibit the late stages of B cell activation by being internalized with Rho antigen by B cells, which alters the antigen processing and presentation. In response to the IgG-antigen complex formation, the immune globulin enhances the presentation of specific peptides and proliferation of epitope-specific T cells [4]. Therapeutic efficacy of Rho (D) immune globulin in chronic immune thrombocytopenic purpura (ITP) may be explained by FcR blockade as well as the increase in the platelet count by substituting antibody-coated RBCs for antibodycoated platelets [2]. In vitro studies of cytokine expression in human monocytes and granulocytes exposed to anti-D coated red blood cells have demonstrated enhanced secretion of interleukin 1 receptor

antagonist resulting in down-regulation of FcγR mediated phagocytosis. Murine models show that



antibody

Human

Absorption

In patients undergoing therapy for Rh isoimmunization suppression, Rho(D) immune globulin titers were detected in all women up to at least 9 weeks following either intravenous or intramuscular administration. Following intravenous administration of a single 1500 IU (300 mcg) dose, peak serum levels of Rh0(D) immune globulin ranged from 62 to 84 ng/mL after first day. The levels ranged from 7 to 46 ng/mL and were achieved between 2 and 7 days following intramuscular injection. The absolute bioavailability achieved following IM administration is 69%.

Volume of distribution

A single dose of 300ug Rho(D) Immune Globulin through intramuscular injection displays a Vd of 8.59L ^[13].

Protein binding

Not Available

Metabolism

Rho (D) immune globulin is expected to undergo nonspecific catabolism.

Route of elimination

Human immune globulin and the fragments can be detected in feces and urine.

Half life

The half life is 16 ± 4 days following IV administration and 18 ± 5 days following IM administration.

Clearance

Mean systemic clearance following IV administration is 0.20 ± 0.03 mL/min. Mean apparent clearance following IM administration is 0.29 ± 0.12 mL/min.

Toxicity

Most serious adverse reactions in patients with ITP include intravascular hemolysis, anemia, acute renal insufficiency, and death. In patients treated for Rh isoimmunization suppression, common adverse effects include nausea, dizziness, headache, pain at injection site and malaise. Common

adverse effects in patients with ITP include chills, pyrexia, mild extravascular hemolysis and headache.

Affected organisms

Not Available



Pharmacogenomic Effects/ADRs [i](#)

Not Available

INTERACTIONS

Drug Interactions [i](#)

Not Available

Food Interactions

Not Available

REFERENCES

General References

1. Cheung E, Liebman HA: Anti-RhD immunoglobulin in the treatment of immune thrombocytopenia. *Biologics*. 2009;3:57-62. Epub 2009 Jul 13. [[PubMed:19707396](#)]
2. Bussel JB, Graziano JN, Kimberly RP, Pahwa S, Aledort LM: Intravenous anti-D treatment of immune thrombocytopenic purpura: analysis of efficacy, toxicity, and mechanism of effect. *Blood*. 1991 May 1;77(9):1884-93. [[PubMed:1850307](#)]
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6. Bichler J, Schondorfer G, Pabst G, Andresen I: Pharmacokinetics of anti-D IgG in pregnant RhD-negative women. *BJOG*. 2003 Jan;110(1):39-45. [[PubMed:12504934](#)]
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10. Arend WP, Silverblatt FJ: Serum disappearance and catabolism of homologous immunoglobulin fragments in rats. *Clin Exp Immunol*. 1975 Dec;22(3):502-13. [[PubMed:1225487](#)]
11. Rhophylac Summary of Basis for Approval [[Link](#)]
12. WinRho Product information [[Link](#)]
13. RhoGam (Rho(D) Immune Globulin intramuscular injection) product information [[Link](#)]

External Links

PubChem Substance

[347911208](#)

Wikipedia



00.04.00 - Serums

FDA label[Download](#) (513 KB)

CLINICAL TRIALS

Clinical Trials

Search

PHASE	STATUS	PURPOSE	CONDITIONS	COUNT
1	Completed	Treatment	Healthy Volunteers	1
Not Available	Completed	Treatment	Dengue Fever	1

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PHARMACOECONOMICS

Manufacturers

Not Available

Packagers

Not Available

Dosage forms

Search

FORM	ROUTE	STRENGTH
Liquid	Intramuscular	16.5 %
Solution	Intramuscular	1500 [iU]/1
Solution	Intramuscular	250 [iU]/1
Injection, solution	Intramuscular	50 ug/1
Injection, solution	Intramuscular	300 ug/1
Solution	Intramuscular; Intravenous	1500 [iU]/2mL
Kit	Intramuscular; Intravenous	
Kit	Intramuscular; Intravenous	1500 unit
Kit	Intramuscular; Intravenous	5000 unit



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Prices

Not Available

Patents

Not Available

PROPERTIES

State

Liquid

Experimental Properties

Not Available

TAXONOMY

Description

Not Available

Kingdom

Organic Compounds

Super Class

Organic Acids

Class

Carboxylic Acids and Derivatives

Sub Class

Amino Acids, Peptides, and Analogues

Direct Parent

Peptides

Alternative Parents

Not Available

Substituents



External Descriptors

Not Available

TARGETS

1. Rhesus blood group D antigen

Kind

Protein

Organism

Human

Pharmacological action

Yes

Actions

Antibody

General Function

Ammonium transmembrane transporter activity

Specific Function

Not Available

Gene Name

RHD

Uniprot ID

[A6PZ59](#)

Uniprot Name

Rhesus blood group D antigen

Molecular Weight

45275.06 Da

Drug created on May 20, 2016 13:42 / Updated on July 31, 2018 07:12

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