

Rhopylac® Rh₀(D) Immune Globulin Intravenous (Human) and Other Rh₀(D) Products Used in the United States: Information From Respective Package Inserts

Brand	Rhopylac® Rh ₀ (D) Immune Globulin Intravenous (Human)	RhoGAM®/MICRhoGAM® Ultra-Filtered Rh ₀ (D) Immune Globulin (Human)	HyperRho™ S/D Full Dose Rh ₀ (D) Immune Globulin (Human)	WinRho® SDF Rh ₀ (D) Immune Globulin Intravenous (Human)
Manufacturer	CSL Behring	Ortho-Clinical Diagnostics	Talecris Biotherapeutics	Cangene/Baxter
Indications	<p>Pregnancy and other obstetric conditions</p> <p>Suppression of rhesus (Rh) isoimmunization in non-sensitized Rh₀(D)-negative women with an Rh-incompatible pregnancy, including:</p> <ul style="list-style-type: none"> • Routine antepartum and postpartum Rh prophylaxis • Rh prophylaxis in cases of: <ul style="list-style-type: none"> –Obstetric complications (eg, miscarriage, abortion, threatened abortion, ectopic pregnancy or hydatidiform mole, transplacental hemorrhage resulting from antepartum hemorrhage) –Invasive procedures during pregnancy (eg, amniocentesis, chorionic biopsy) or obstetric manipulative procedures (eg, external version, abdominal trauma) <p>Incompatible transfusions</p> <p>For the suppression of Rh isoimmunization in Rh₀(D)-negative individuals transfused with Rh₀(D)-positive red blood cells or blood components containing Rh₀(D)-positive red blood cells.</p> <p>Immune thrombocytopenic purpura (ITP)</p> <p>For Rh₀(D)-positive, non-splenectomized adult patients with chronic ITP to raise platelet counts.</p>	<p>Pregnancy and other obstetric conditions</p> <p>Prevention of rhesus (Rh) isoimmunization in Rh₀(D)-negative women unless the father or baby are conclusively Rh-negative in the following circumstances:</p> <ul style="list-style-type: none"> • Pregnancy/delivery of an Rh-positive baby irrespective of the ABO groups of the mother and baby • Abortion/threatened abortion at any stage of gestation • Ectopic pregnancy • Antepartum fetal-maternal hemorrhage (suspected or proven) resulting from antepartum hemorrhage (eg, placenta previa), amniocentesis, chorionic villus sampling, percutaneous umbilical blood sampling, other obstetric manipulative procedure (eg, version), or abdominal trauma <p>Transfusion</p> <p>Prevention of Rh immunization in any Rh-negative person after incompatible transfusion of Rh-positive blood or blood products (eg, red blood cells, platelet concentrates, granulocyte concentrates).</p>	<p>Pregnancy and other obstetric conditions</p> <p>To prevent Rh hemolytic disease of the newborn (HDN) by administration to a non-sensitized Rh₀(D)-negative mother within 72 hours of birth of an Rh₀(D)-positive infant or within 72 hours of the following obstetric conditions involving a fetus that is known to be or to possibly be Rh₀(D)-positive: spontaneous or induced abortion, ruptured tubal pregnancy, or abdominal trauma.</p> <p>Transfusion</p> <p>To prevent isoimmunization in Rh₀(D)-negative individuals who have been transfused with Rh₀(D)-positive red blood cells or blood components containing red blood cells.</p>	<p>Pregnancy and other obstetric conditions</p> <p>Suppression of Rh isoimmunization in non-sensitized Rh₀(D)-negative women carrying a baby not known to be Rh-negative through administration within 72 hours after spontaneous or induced abortions, amniocentesis, chorionic villus sampling, ruptured tubal pregnancy or transplacental hemorrhage, or in the normal course of pregnancy.</p> <p>Transfusion</p> <p>For the suppression of Rh isoimmunization in Rh₀(D)-negative female children and female adults in their childbearing years transfused with Rh₀(D)-positive red blood cells or blood components containing Rh₀(D)-positive red blood cells.</p> <p>Treatment of immune thrombocytopenic purpura (ITP)</p> <p>For the treatment of non-splenectomized, Rh₀(D)-positive</p> <ul style="list-style-type: none"> • Children with chronic or acute ITP • Adults with chronic ITP • Children and adults with ITP secondary to HIV infection
Contraindications	Individuals known to have had an anaphylactic or severe systemic reaction to the administration of human immune globulin products.	Individuals known to have had an anaphylactic or severe systemic reaction to human globulin.	None known.	In suppression of Rh isoimmunization, Rh ₀ (D) should not be administered to the infant. Individuals known to have had an anaphylactic or severe systemic reaction to human globulin. Individuals who are deficient in IgA may have the potential for developing IgA antibodies and have anaphylactic reactions.
Warnings	Rhopylac® is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. ITP: Intravascular hemolysis has been seen in a clinical study with Rhophylac®. All cases resolved completely. However, as reported in the literature, some patients treated with Rh ₀ (D) immune globulin (anti-D) developed clinically compromising anemia, acute renal insufficiency, and, very rarely, disseminated intravascular coagulation (DIC) and death. Following administration of Rhophylac®, patients should be monitored for signs and/or symptoms of intravascular hemolysis and its complications including clinically compromising anemia, acute renal insufficiency, and DIC.	RhoGAM® and MICRhoGAM® are made from human plasma. Because these products are made from human blood, they may carry a risk of transmitting infectious agents, including viruses and, theoretically, the CJD agent.	HyperRho™ S/D Full Dose is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The attending physician who wishes to administer Rh ₀ (D) Immune Globulin (Human) to persons with isolated IgA deficiency must weigh the benefits of immunization against the potential risks of hypersensitivity reactions. Such persons have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA. Never administer intravenously or to the neonate. Inject only intramuscularly. As with all preparations administered by the intramuscular route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.	WinRho® SDF is made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, including viruses and, theoretically, the CJD agent. In ITP, there have been post-marketing reports of intravascular hemolysis that include back pain, shaking, chills, fever, and discolored urine. The liquid formulation of WinRho® SDF contains maltose. Maltose in IVIG products has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems.
Adverse events	The most common adverse events observed in use for suppression of Rh isoimmunization are nausea, dizziness, headache, injection-site pain, and malaise. The most serious adverse events in patients receiving Rh ₀ (D) immune globulin have been observed in the treatment of ITP, including intravascular hemolysis, clinically compromising anemia, acute renal insufficiency, and, very rarely, DIC and death. The most common adverse events in use of Rhophylac® for ITP are chills, fever, and headache.	Most frequently reported adverse reactions are anti-D formation and skin reactions, such as swelling, induration, redness, and mild pain at the site of injection. Systemic allergic reactions occur rarely, and as with any Rh ₀ (D) immune globulin (Human), administration to patients who have received Rh-positive red blood cells may result in signs and symptoms of a hemolytic reaction.	The most common adverse events are slight soreness at injection site and slight temperature elevation.	The most serious adverse events have been in patients receiving WinRho SDF for the treatment of ITP. These include intravascular hemolysis, clinically compromising anemia, acute renal insufficiency, and, very rarely, DIC and death. The most common adverse events for all indications are headaches, chills, fever, and nausea.
Precautions	Suppression of Rh isoimmunization: Rhophylac® should not be given to the newborn infant. Allergic reactions may occur. If symptoms of allergic or early signs of hypersensitivity reactions (including generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis) occur, immediately discontinue administration. Individuals with selective IgA deficiency can develop antibodies to IgA and anaphylactic reactions (including anaphylaxis and shock) after administration of blood components containing IgA. Although the concentration of IgA was found to be below the detection limit of 5 mcg/mL, Rhophylac® may contain trace amounts of IgA. The administration of Rh ₀ (D) immune globulin may affect the results of blood typing, the antibody screening test, and the direct antiglobulin (Coombs') test.	For intramuscular use only. Do not inject RhoGAM® or MICRhoGAM® intravenously. In the case of postpartum use, the product is intended for maternal administration. Do not inject the newborn infant. Patients should be observed for at least 20 minutes after administration. Allergic responses to RhoGAM® or MICRhoGAM® may occur. Patients should be informed of the early signs of hypersensitivity reactions. RhoGAM® and MICRhoGAM® contain a small quantity of IgA (less than 15 mcg per dose). Although high doses of intravenous immunoglobulin containing IgA at levels of 270-720 mcg/mL have been given without incident during treatment of patients with high-titered antibodies to IgA, the attending physician must weigh the benefit against the potential risks of hypersensitivity reactions. Fetal-maternal hemorrhage may cause false blood typing results in the mother. When there is any doubt as to the patient's Rh type, RhoGAM® or MICRhoGAM® should be administered.	A large fetomaternal hemorrhage late in pregnancy or following delivery may cause a weak mixed field positive D ⁺ test result. If there is any doubt about the mother's Rh type, she should be given Rh ₀ (D) Immune Globulin (Human). If more than 15 mL of D-positive red blood cells are present in the mother's circulation, more than a single dose is required.	General Intravenous immune globulin (human) products have been reported to produce renal dysfunction in patients that are predisposed to acute renal failure or those with renal insufficiency. Suppression of Rh Isoimmunization WinRho® SDF should not be administered to Rh ₀ (D)-negative individuals who are Rh immunized as evidenced by an indirect antiglobulin (Coombs') test revealing the presence of anti-Rh ₀ (D) (anti-D) antibody. A large fetomaternal hemorrhage late in pregnancy or following delivery may cause a weak mixed field positive D ⁺ test result. WinRho® SDF should be administered if there is any doubt about the father's blood type. Treatment of ITP Patients should be monitored for signs and/or symptoms of intravascular hemolysis and its complications including clinically compromising anemia, acute renal insufficiency, and DIC.
Route of administration	Suppression of Rh isoimmunization: Intravenous or intramuscular injection ITP: Must be administered intravenously	Intramuscular injection only	Intramuscular administration only	Suppression of Rh isoimmunization: May be administered intramuscularly or intravenously ITP: Must be administered intravenously
Other ingredients (concentration as in reconstituted solution)	<ul style="list-style-type: none"> • NaCl up to 0.25 M • Albumin 10 mg/mL • Glycine approximately 20 mg/mL • No preservative • Latex free 	<ul style="list-style-type: none"> • NaCl approximately 2.9 mg/mL • Polysorbate 80 0.01% • Glycine 15 mg/mL • No preservative • Latex free 	<ul style="list-style-type: none"> • Glycine 0.21-0.32 M • No preservative 	<p>Lyophilized:</p> <ul style="list-style-type: none"> • 0.1 M glycine • 0.04 M sodium chloride • 0.01% polysorbate 80 <p>Liquid:</p> <ul style="list-style-type: none"> • 10% maltose • 0.03% polysorbate 80 <p>There are no preservatives in either formulation</p>
Immune globulin A (IgA) content	Less than limit of detection (<5 mcg/mL)	Typically less than 15 mcg/dose	Not specified	Approximately 5 mcg/mL
Method of manufacture	Ion exchange chromatography	Cold ethanol fractionation	Cold ethanol fractionation	Anion-exchange column chromatography
Viral safety process	Solvent/detergent & nanofiltration (Planova® 15 nm)	Ultrafiltration Viresolve™ 180 (12-18 nm)	Solvent/detergent treatment	Solvent/detergent treatment & nanofiltration (Planova® 20 nm)
Formulation	Sterile solution (in ready-to-use, prefilled syringes)	Sterile solution (prefilled syringes)	Sterile solution (in single-dose syringes with attached needles and vials)	Sterile, lyophilized, or liquid gamma globulin (IgG). See reconstitution chart in WinRho® SDF prescribing information.
Unit size (per syringe)	At least 1500 IU (300 mcg) in 2 mL solution	Approximately 300 mcg RhoGAM® Approximately 50 mcg MICRhoGAM®	≥1500 IU	300 mcg (1500 IU) 500 mcg (2,500 IU)-liquid only 1000 mcg (5,000 IU) 3000 mcg (15,000 IU)-liquid only
Clearance of Rh-positive red blood cells	At least 15 mL/dose	RhoGAM® 15 mL or less/dose MICRhoGAM® 2.5 mL or less/dose	15 mL/dose	Approximately 17 mL/dose
Storage	2°-8°C (do not freeze; protect from light)	2°-8°C (do not store frozen)	2°-8°C (do not freeze)	2°-8°C (do not freeze)

Please see Important Safety Information on back of card and enclosed full Prescribing Information for Rhophylac®.
Please see each product's full prescribing information for detailed information on indications and safety.

Rhophylac[®]

Rh₀(D) Immune Globulin Intravenous (Human)

For intravenous or intramuscular injection.

Important Safety Information

Rhophylac[®] is indicated for suppression of rhesus (Rh) isoimmunization in:

- **Pregnancy and obstetric conditions** in non-sensitized, Rh₀(D)-negative women with an Rh-incompatible pregnancy, including routine antepartum and postpartum Rh prophylaxis and Rh prophylaxis in cases of obstetric complications, invasive procedures during pregnancy, or obstetric manipulative procedures.
- **Incompatible transfusions** in Rh₀(D)-negative individuals transfused with blood components containing Rh₀(D)-positive red blood cells.

For suppression of Rh isoimmunization, Rhophylac[®] **can be administered IM or IV.**

Rhophylac[®] is indicated to raise platelet counts in Rh₀(D)-positive, non-splenectomized adult patients with chronic immune thrombocytopenic purpura (ITP). For the treatment of ITP, Rhophylac[®] **must be administered IV.**

Rhophylac[®] is contraindicated in individuals with known anaphylactic or severe systemic reaction to human immune globulin products.

Allergic or hypersensitivity reactions may occur with Rhophylac[®]; early signs of hypersensitivity include generalized urticaria, chest tightness, wheezing, hypotension, and anaphylaxis. Individuals with selective IgA deficiency can develop antibodies to IgA and may develop severe hypersensitivity and anaphylactic reactions. For these individuals, weigh the expected benefits of treatment against the potential risks.

Rhophylac[®] is derived from human plasma. As with all plasma-derived products, the risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, cannot be completely eliminated.

Suppression of Rh Isoimmunization: For postpartum use following an Rh-incompatible pregnancy, Rhophylac[®] should not be given to the newborn infant.

The most common adverse reactions in the suppression of Rh isoimmunization with Rhophylac[®] are nausea, dizziness, headache, injection-site pain, and malaise.

Immune Thrombocytopenic Purpura: The most serious adverse reactions in patients receiving Rh₀(D) immune globulin have been observed in the treatment of ITP. ITP patients being treated with Rhophylac[®] should be monitored for signs and symptoms of intravascular hemolysis, including back pain, shaking chills, fever, and hemoglobinuria. Potentially serious complications of intravascular hemolysis include clinically compromising anemia, acute renal insufficiency, and, very rarely, disseminated intravascular coagulation, and death.

The most common adverse reactions observed in the treatment of ITP are chills, pyrexia/increased body temperature, and headache. Mild extravascular hemolysis has also been observed. In patients with preexisting anemia, weigh the benefits of Rhophylac[®] against the potential risk of increasing the severity of the anemia.

For more information about Rhophylac[®], please contact:

Customer Support: **1.800.683.1288**

Medical Information: **1.800.504.5434**

Reimbursement Answerline: **1.800.676.4266**

www.rhophylac.com

Please see enclosed full Prescribing Information for Rhophylac[®].

Please see full Prescribing Information for each product named herein for detailed information on their respective indications and safety.

CSL Behring

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