Rho(D) Immune Globulin

Product Specifics	HyperRHO® S/D Grifols	RhoGAM® Kedrion	Rhophylac® CSL Behring	WinRho SDF Liquid® Saol Therapeutics
Indications	Mini-Dose: For prevention of isoimmunization in Rho(D) negative women at the time of spontaneous or induced abortion of up to 12 weeks' gestation. Full Dose: For prevention of Rh hemolytic disease of the newborn by its administration to the Rho(D) negative mother within 72 hours after birth of an Rho(D) positive infant, and to prevent isoimmunization in Rho(D) negative individuals who have been transfused with Rho(D) positive red blood cells or blood components containing red blood cells.	For use in preventing Rh immunization. Pregnancy and other obstetrical conditions in Rh-negative women unless the father or baby are conclusively Rh-negative, e.g. delivery of an Rh-positive baby irrespective of the ABO groups of the mother and baby, any antepartum fetal-maternal hemorrhage (suspected or proven), actual or threatened pregnancy loss at any stage of gestation and ectopic pregnancy. Prevention of Rh immunization in any Rh-negative person after incompatible transfusion of Rh-positive blood or blood products.	Suppression of rhesus (Rh) isoimmunization in non-sensitized Rho(D)-negative women with an Rh-incompatible pregnancy. Suppression of Rh isoimmunization in Rho(D)-negative individuals transfused with Rho(D)-positive red blood cells (RBCs) or blood components containing Rho(D)-positive RBCs. Indicated in Rho(D)-positive, non-splenectomized adult patients with chronic ITP to raise platelet counts.	Children with chronic or acute ITP, adults with chronic ITP, or children and adults with ITP secondary to HIV infection, and suppression of Rh Isoimmunization
Contraindications	None known. Rho(D) Immune Globulin (Human) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations. The attending physician who wishes to administer Rho(D) Immune Globulin (Human) to persons with isolated immunoglobulin A (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. As with all preparations administered by the intramuscular route, bleeding complications may be encountered in patients with thrombocytopenia or other bleeding disorders.	The use of RhoGAM and MICRhoGAM is contraindicated in Rh-positive individuals.	Rhophylac is contraindicated in individuals with known anaphylactic or severe systemic reaction to human immune globulin products. Rhophylac is contraindicated in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity. Do not administer Rhophylac to the newborn infant of a mother that received Rhophylac postpartum.	WinRho is contraindicated in: Patients who have had known anaphylactic or severe systemic reaction to the administration of human immune globulin products. IgA deficient patients with antibodies to IgA and a history of hypersensitivity. Patients with autoimmune hemolytic anemia, with pre-existing hemolysis or at high risk for hemolysis. Infants for the suppression of Rho(D) isoimmunization
Viral Safety Processes	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperRho® S/D contributes to virus inactivation. Manufacturing process includes steps that provide significant removal (≥ 6.7 log10) of TSE infectivity.	RhoGAM® Brand uses a unique plasma collection center which draws from a pool of approximately 500 donors. Fractionation, filtration (Viresolve® 180 ultrafiltration) and solvent/detergent treatment removes and inactivates both enveloped and non-enveloped viruses including Hepatitis A and West Nile.	Solvent/Detergent, Chromatographic process steps, and Nanofiltration (Planova® 15 nM) (For additional details on viral safety, please see full prescribing information.)	Solvent/Detergent, nanofiltration, anion exchange column chromatography
Route of Administration	Intramuscular	Intramuscular	Either IV or IM for suppression of Rh isoimmunization. For treatment of ITP, Rhophylac® must be administered IV.	IV or IM depending on indication
Clearance of Rh-positive Red Blood Cells	* Mini-Dose: Each single dose syringe contains sufficient anti-Rho(D) to effectively suppress the immunizing potential of 2.5 mL of Rho(D) positive packed red blood cells or the equivalent of whole blood (5 mL).* Full Dose: Each single dose syringe contains sufficient anti-Rho(D) to effectively suppress the immunizing potential of 15 mL of Rho(D) positive red blood cells.	15 mL packed red blood cells	A 1500 IU (300 mcg) dose of Rhophylac will suppress the immunizing potential of ≤15 mL of Rh0(D)-positive RBCs	A 1,500 IU dose will suppress the immunizing potential of approximately 17 mL of RhoD positive RBC's.
Product Half Life	The half-life of IgG in the circulation of individuals with normal IgG levels is approximately 23 to 26 Days.	30.9 days	16 ± 4 days for IV administration, 18 ± 5 days for IM administration	24 days IV, 30 days IM
Latex Content	None	None	None	None
Thimerosal Content	None	None	None	None
Storage Requirements	2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used.	Store at 2 to 8°C. Do not store frozen. Do not use after the expiration date printed on the syringe.	Store refrigerated at 2-8°C (36-46°F). Do not freeze. Protect from light.	Refrigeration 2°-8°C (36°-46°F); Do not freeze.
Shelf Life from Date of Manufacture	36 months	3 years / Please check your inventory as some 2 year product is still available.	36 months	36 months
How Supplied	Preservative (thimerosol)-free, prefilled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system. * Mini-Dose: 250 IU pfs in 10pk * Full Dose: 1,500 IU pfs in 10pk and single syringe	Pre-filled syringe. Ready to use. 1 package insert, 1 control form, 1 patient identification card. RhoGAM Ultra-Filtered PLUS package sizes: 1 prefilled single-dose syringe of RhoGAM 5 prefilled single-dose syringes of RhoGAM 25 prefilled single-dose syringes of RhoGAM MICRhoGAM Ultra-Filtered PLUS package sizes: 1 prefilled single-dose syringe of MICRhoGAM 5 prefilled single-dose syringes of MICRhoGAM 25 prefilled single-dose syringes of MICRhoGAM	2 mL Prefilled syringe, ready to use.	Single Vial: 1,500 IU (300 mcg), 2,500 IU (500 mcg), 5,000 IU (1,000 mcg), 15,000 IU (3,000 mcg)