

Products Indicated for ITP



800.948.9834 ■ www.bdipharma.com

PRODUCT SPECIFICS	Anti-D Products		Intravenous Immune Globulins			
	Rhophylac®	WinRho SDF Liquid	Privigen®	Carimune® NF Nanofiltered	Gamunex-C®	Gammaked®
INDICATIONS	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	Primary Immunodeficiency (PI), Chronic Immune Thrombocytopenic Purpura (ITP)	Primary Immune Deficiency (PID), Acute ITP, Chronic ITP	CIDP, PI, ITP	CIDP, PI, ITP
CONTRAINDICATIONS	Individuals known to have had an anaphylactic or severe systemic reaction to the administration of human immune globulin products.	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	Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. Patients with hyperprolinemia. Patients with selective IgA deficiency with antibodies to IgA.	Contraindicated in patients with selective IgA deficiency, who possess antibody to IgA. It may also be contraindicated in patients who have had severe systemic reactions to intravenous or intramuscular administration of human immune globulin.	Individuals with known anaphylactic or severe systemic response to IG. Individuals with known antibodies against IgA should receive Gamunex-C® with utmost cautionary measures due to risk of severe immediate hypersensitivity reactions including anaphylaxis.	Individuals with known anaphylactic or severe systemic response to IG. Individuals with known antibodies against IgA should receive Gammaked® with utmost cautionary measures due to risk of severe immediate hypersensitivity reactions including anaphylaxis.
VIRAL SAFETY PROCESS	Solvent/Detergent and Nanofiltration (Planova® 15 nM)	Solvent/Detergent, nanofiltration, anion exchange column chromatography	pH 4 incubation, 20nm virus filtration, and depth filtration; TSE validation and removal	pH 4.0 + trace pepsin, nanofiltration, fractionation, depth filtration, TSE reduction	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Low pH Incubation	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Low pH Incubation
ROUTE OF ADMINISTRATION	Either IV or IM for suppression of Rh isoimmunization. For treatment of ITP, Rhophylac® must be administered IV.	IV or IM depending on indication	Intravenous (IV)	Intravenous (IV)	Intravenous (IV): CIDP, PI, ITP. Check prescribing information for initial and maintenance infusion rates. Subcutaneous (SC): PI. Initial rate 20 mL/hr/site. Over time, the dose may need to be adjusted to achieve the desired clinical response and serum IG trough level.	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI.
PRODUCT HALF LIFE	16 ± 4 days for IV administration, 18 ± 5 days for IM administration	24 days IV, 30 days IM	36.6 days	21 days	Approximately 35 days	Approximately 35 days
LATEX CONTENT	No	No	No	No	No	No
THIMEROSAL CONTENT	No	No	No	No	No	No
STORAGE REQUIREMENTS	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	Store at room temperature up to 25°C (77°F) for up to 36 months, as indicated by the expiration date printed on the outer carton and vial label. Do not freeze. Protect from light.	Store at room temperature not exceeding 30°C (86°F).	36 months at refrigerated temperature 2°-8°C (36°-46°F). Do not freeze. 6 months at temperatures not to exceed 25°C (77°F) anytime during the 36-month shelf life.	36 months at refrigerated temperature 2°-8°C (36°-46°F). Do not freeze. 6 months at temperatures not to exceed 25° (77°F) anytime during the 36-month shelf life.
SHELF LIFE FROM DATE OF MANUFACTURE	36 months	36 months	36 months	24 months	36 months. Do not use after the labeled expiration date	36 months. Do not use after the labeled expiration date
FORMULATION	Liquid	Liquid	10% Liquid	Lyophilized powder	10% Liquid	10% Liquid
HOW SUPPLIED	Prefilled syringe, ready to use	Vial	Single use, tamper evident vial	Single use, tamper evident vial	Vial	Vial
AVAILABLE SIZES	2 mL prefilled syringes	1500, 2500, 5000, 15000 IU	5 g (50 mL), 10 g (100 mL), 20 g (200 mL)	3 g, 6 g, and 12 g vials	1g (10 mL), 2.5g (25 mL), 5g (50 mL), 10g (100 mL), 20g (200 mL)	1g (10 mL), 2.5g (25 mL), 5g (50 mL), 10g (100 mL), 20g (200 mL)

IMPORTANT NOTICE - The information provided herein is a summary of available information only. This summary is to be used as a general educational tool and is not intended for use as a guideline for clinical evaluations. Such evaluations (including but not limited to initial and/or subsequent dosing, conversions from specific product brands, etc.) should utilize a thorough review of appropriate clinical data. For a copy of a product insert or to request any additional information at our disposal, please contact us at 1-800-948-9834. The possibility of error (typographical or otherwise) exists in this summary. No liability is assumed by the distributor for improper use of this literature. ©2011. BDI Pharma, Inc. All rights reserved.