

# Hyper-Immune Products



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PRODUCT SPECIFICS	Cytomegalovirus	IMIG	Tetanus	Rabies		Hepatitis B		
	CytoGam®	GamaSTAN® S/D	HyperTET® S/D	HyperRAB® S/D	IMOGAM® Rabies-HT	HyperHEP B® S/D	HepaGam B	Nabi-HB®
INDICATIONS	Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with Ganciclovir.	Hepatitis A post-exposure prophylaxis, rubella, rubeola, varicella, immunoglobulin deficiency	Prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain; in the regimen of treatment of active cases of tetanus	Rabies post-exposure prophylaxis	Rabies Immune Globulin (Human) Heat Treated, Imogam® Rabies – HT, is indicated for individuals suspected of exposure to rabies, particularly severe exposure, with one exception: persons who have been previously immunized with Rabies Vaccine prepared from human diploid cells (HDCV) in a pre-exposure or post-exposure treatment series should receive only vaccine.	Post-exposure prophylaxis in the following situations: Acute Exposure to Blood Containing HBsAg, Perinatal Exposure of Infants Born to HBsAg-Positive Mothers, Sexual Exposure to an HBsAg-Positive Person, Household Exposure to Persons with Acute HBV Infection	1) Prevention of Hepatitis B virus (HBV) recurrence following liver transplantation in HBsAg-positive patients (LT indication) 2) Post-exposure prophylaxis in the following settings (PEP indication): i) Acute exposure to infants born to HBsAg-positive mothers ii) Perinatal exposure of infants born to HBsAg-positive mothers iii) Sexual exposure to HBsAg-positive persons iv) Household exposure to persons with acute HBV infection	Indicated for treatment of acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute HBV infection
CONTRAINDICATIONS	Individuals with a history of prior severe reaction associated with the administration of this or other human immunoglobulin preparations. Persons with selective immunoglobulin A deficiency have the potential for developing antibodies to immunoglobulin A and could have anaphylactic reactions to subsequent administration of blood products that contain immunoglobulin A, including CytoGam®.	Patients with isolated IgA deficiency. GamaSTAN® S/D should not be administered to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections	None known. HyperTET® S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperTET® S/D should be given only if the expected benefits outweigh the risks.	None known. HyperRAB® S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. The attending physician who wishes to administer HyperRAB® S/D 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	Imogam® Rabies – HT should NOT be administered in repeated doses once vaccine treatment has been initiated. Imogam® Rabies – HT should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin. Persons with specific IgA deficiency have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products containing IgA.	None known. HyperHEP B® S/D should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations. Epinephrine should be available. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Hepatitis B Immune Globulin (Human) should be given only if the expected benefits outweigh the risks.	Individuals known to have had an anaphylactic or severe systemic reaction to human globulin. Individuals who are deficient in IgA may have the potential to develop IgA antibodies and have an anaphylactoid reaction. In patients who have severe thrombocytopenia or any coagulation disorders that would contraindicate intramuscular injections.	Individuals who are known to have had an anaphylactic or severe systemic reaction to human globulin. Individuals who are deficient in IgA.
VIRAL SAFETY PROCESS	Ethanol precipitation according to Cohn Methods 6 and 9 and Solvent/Detergent treatment	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of GamaSTAN® S/D contributes to virus inactivation.	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperTET® S/D contributes to virus inactivation.	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperRAB® S/D contributes to virus inactivation.	The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. An alcohol fractionation procedure used to purify the immunoglobulin component removes and/or inactivates both enveloped and non-enveloped viruses to a certain extent. An added heat treatment process (60°C, 10 hours) further inactivates both enveloped and non-enveloped viruses.	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperHEP B® S/D contributes to virus inactivation.	Solvent/Detergent treatment - inactivation of enveloped viruses 20 nm Viral filtration - effective for the removal of viruses based on their size, included are some non-enveloped viruses	Solvent/Detergent treatment - inactivation of enveloped viruses Viral filtration - viral removal
ROUTE OF ADMINISTRATION	Intravenous (IV)	Intramuscular	Intramuscular	Intramuscular. Infiltrate wound site with as much as anatomically feasible, remaining portion, if any, administered IM at an anatomical site distant from vaccine administration.	If anatomically feasible, the full dose of Rabies Immune Globulin (Human) (RIGH) should be thoroughly infiltrated in the area around and into the wounds. Any remaining volume should be injected intramuscularly, using a separate needle, at a site distant from vaccine administration.	Intramuscular	The administration of HepaGam B is indication dependent. It is administered Intravenously to treat the LT indication and Intramuscularly (IM) to treat the PEP indication	Intramuscular (IM)
POTENCY	50 ± 10 mg/mL	Varies according to indication for use. Contact Grifols Medical Information at 1-800-520-2807 if you have specific potency questions.	Minimum of 250 AU (anti-toxin units)/syringe	Average 150 IU/mL	150 IU per mL	Minimum 220 IU/mL	A minimum potency of > 312 IU/mL. The measured potency of each lot is also stamped on the vial label	≥ 312 IU/mL
PROTEIN CONCENTRATION	5%	15-18% protein solution	15-18% protein solution	15-18% protein solution	10-18% protein	15-18% protein solution	5%	5%
PRODUCT HALF LIFE	Ranges from 8 - 24 days	The half-life of IgG in the circulation of individuals with normal IgG levels is 23 Days	The half-life of IgG in the circulation of individuals with normal IgG levels is 23 Days	Detectable passive rabies antibody titers were observed in the serum by 24 hours post injection and persisted for 21 days, following the IM administration of 20 IU/kg HyperRAB® S/D.	Not applicable	Mean values between 17.5 and 25 days (range 5.9 - 35 days)	24.5 ± 4.6 days	23.1 ± 5.5 days
STORAGE REQUIREMENTS	Store between 2°-8°C (36°-46°F)	2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used	2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used	2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used	2° to 8°C (35° to 46°F). DO NOT FREEZE.	2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used	Refrigeration 2°-8°C (36°-46°F); Do not freeze.	Refrigeration 2°-8°C (36°-46°F); Do not freeze.
SHELF LIFE FROM DATE OF MANUFACTURE	24 months	36 months	36 months	30 months	36 months-must use by expiration date on vial	36 months	36 months	39 months
FORMULATION	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
HOW SUPPLIED	Single-dose vial	Preservative (thimerosal)-free, latex-free single dose vials	Preservative (thimerosal)-free, prefilled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system	Preservative (thimerosal)-free, latex-free single dose vials	Vial	* 0.5 mL neonatal and 1 mL preservative-free, prefilled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system * 1 mL preservative-free, latex-free single-dose vials * 5 mL preservative-free, latex-free single-dose vials	Single-dose vial	Single-dose vial
AVAILABLE SIZES	50 mL (2.5 g)	2 mL, 10 mL	250 unit prefilled disposable syringe	2 mL, 10 mL	2 mL vial	* 0.5 mL neonatal and 1 mL preservative-free, prefilled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system * 1 mL preservative-free, latex-free single-dose vials * 5 mL preservative-free, latex-free single-dose vials	1 mL, 5 mL	1 mL, 5 mL

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