

Product Specifics	IMIG	Tetanus	Rabies	Hepatitis B			Cytomegalovirus
	GamaSTAN™ S/D	HyperTET™ S/D	HyperRAB™ S/D	HyperHEP B™ S/D	HepaGam B	Nabi-HB®	Cytogam
Indications	Hepatitis A post-exposure prophylaxis, rubella, 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	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	Prevention of Hepatitis B reoccurrence following Liver Transplantation. Post exposure Prophylaxis in the following settings: -Acute Exposure to Blood Containing HBsAg -Perinatal Exposure of Infants Born to HBsAg-positive Mothers -Sexual Exposure to HBsAg-Positive Persons -Household Exposure to Persons with Acute HBV Infection	Prophylaxis for the prevention of Hepatitis B following acute exposure to HBsAg blood, HBsAg positive mothers/sexual partners or persons with acute HBV infection	Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart
Contraindications	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	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.	History of anaphylactic or severe systemic reactions to human globulins. IgA deficient individuals may have the potential to develop IgA antibodies and have an anaphylactoid reaction. IM injections may be contraindicated in patients with coagulation disorders.	Individuals who are known to have had an anaphylactic or severe systemic reaction to human globulin, IgA deficiency	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®.
Viral Safety Processes	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.	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperHEP B™ S/D contributes to virus inactivation.	The manufacturing process contains two steps implemented specially for virus clearance. The solvent and detergent step (using tri-n-butyl phosphate and Triton X-100) is effective in the inactivation of enveloped viruses, such as HEP B, HIV, and HEP C. Virus filtration, using Planova 20N virus filter is effective for the removal of viruses based on their size, and some non-enveloped viruses.	Solvent/Detergent treatment - inactivation of enveloped viruses. Viral filtration -viral removal	Ethanol precipitation according to Cohn Methods 6 and 9 and Solvent/Detergent treatment
Route of Administration	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.	Intramuscular	Both IV and IM for Liver Transplantation and IM for Post Exposure	Intramuscular (IM)	Intravenous (IV)
Potency	Varies according to indication for use. Contact Talecris Clinical Communications at 1-800-520-2807 if you have specific potency questions.	Minimum of 250 AU (anti-toxin units)/syringe	Average 150 iu/mL	Minimum 220 iu/mL	Varies but greater than or equal to 312 iu/mL. The exact potency is stamped on each vial.	≥ 312 iu/mL	50 ± 10 mg/mL
Protein Concentration	15-18% protein solution	15-18% protein solution	15-18% protein solution	15-18% protein solution	5%	5%	5%
Product Half Life	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.	Mean values between 17.5 and 25 days (range 5.9 - 35 days)	22 to 25 days	23.1 ± 5.5 days	Ranges from 8-24 days
Storage Requirements	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°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used	Store at 36°-46° F. Do not freeze. Do not use after expiration date. Use within 6 hours after the vial has been entered.	Refrigeration 2°-8°C (36°-46°F); Do not freeze.	Store between 2°-8°C (36°-46°F)
Shelf Life from Date of Manufacture	36 months	36 months	30 months	36 months	36 months	39 months	24 months
Formulation	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
How Supplied	Preservative (thimerosal)-free, latex-free single dose vials	Preservative (thimerosal)-free, pre-filled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system	Preservative (thimerosal)-free, latex-free single dose vials	* 0.5 mL neonatal and 1 mL preservative-free, pre-filled 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	Vial	Single-dose vial	Single-dose vial
Available Sizes	2 mL, 10 mL	250 unit pre-filled disposable syringe	2 mL, 10 mL	* 0.5 mL neonatal and 1 mL preservative-free, pre-filled 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 and 5 mL	1 mL, 5 mL	50 mL (2.5 gm)

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