Hyper-Immune Globulin

Product Specifics	IMIG		Tetanus	Rabies		Hepatitis B		
	Varizig Aptevo	**GamaSTAN® S/D** Grifols	**HyperTET® S/D** Grifols	**HyperRAB® S/D** Grifols	**IMOGAM® Rabies-HT** Sanofi	**HepaGam B** Aptevo	**HyperHEP B® S/D** Grifols	**Nabi-HB®** Biotest
Indications	Indicated for postexposure prophylaxis in high risk individuals (1). High risk groups include: • Immunocompromised children and adults • Newborns of mothers with varicella shortly before or after delivery • Premature infants • Infants less than one year of age • Adults without evidence of immunity pregnant women. VARIZIG administration is intended to reduce the severity of varicella.	Hepatitis A post-exposure prophylaxis, rubeola, rubella, varicella	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.	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 blood containing HBsAg 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	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	Prophylaxis for the prevention of Hepatitis B following acute exposure to HBsAg blood, HBsAg positive mothers/sexual partners or persons with acute HBV infection
Contraindications	• Individuals known to have anaphylactic or severe systemic (hypersensitivity) reactions to human immune globulin preparations should not receive VARIZIG. • IgA-deficient patients with antibodies against IgA and a history of hypersensitivity may have an anaphylactoid reaction. • VARIZIG contains less than 40 micrograms per milliliter of IgA.	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.	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 anaphylactiod reaction. In patients who have severe thrombocytopenia or any coagulation disorders that would contraindicate intramuscular injections.	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 who are known to have had an anaphylactic or severe systemic reaction to human globulin, IgA deficiency.
Viral Safety Processes	The manufacturing process contains two steps implemented specifically for virus clearance. The solvent/detergent step (using tri-n-butyl phosphate and Triton® X-100) is effective in the inactivation of enveloped viruses, such as HBV, HCV and HIV-1. Virus filtration, using a Planova® 20N virus filter, is effective for the removal of viruses based on their size, including some non-enveloped viruses.	Precipitation, Depth Filtration, Solvent/ Detergent Treatment. The final container incubation step used during the manufacture of GamaSTAN® S/D contributes to virus inactivation. Manufacturing process includes steps that provide significant removal (≥ 6.7 log10) of TSE infectivity.	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperTET® S/D contributes to virus inactivation. Manufacturing process includes steps that provide significant removal (≥ 6.7 log10) of TSE infectivity.	Precipitation, Depth Filtration, Solvent/Detergent Treatment. The final container incubation step used during the manufacture of HyperRAB® S/D contributes to virus inactivation. Manufacturing process includes steps that provide significant removal (≥ 6.7 log10) of TSE infectivity.	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.	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. Anion-exchange chromatography contrbutes to overall viral clearance capacity for small 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. Manufacturing process includes steps that provide significant removal (≥ 6.7 log10) of TSE infectivity.	Solvent/Detergent treatment - inactivation of enveloped viruses Viral filtration - viral removal
Route of Administration	For intramuscular administration only	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.	The administration of HepaGam B is indication dependent. It is recommended to administer HepaGam B intravenously for the LT indication and intramuscularly for the PEP indication.	Intramuscular	Intramuscular (IM)
Potency	Each vial of VARIZIG contains a minimum potency of 125 IU in 1.2 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	A minimum potency of > 312 IU/mL. The measured potency of each lot is also stamped on the the vial label. A potency of 550 IU/mL is targeted at the time of manufacture.	Minimum 220 IU/mL	312 IU/mL
Protein Concentration	Need this… is it 10%	15 - 18% protein solution	15 - 18% protein solution	15 - 18% protein solution	10 - 18% protein	5%	15 - 18% protein solution	5%
Product Half Life	26.2 ± 4.6 days (The half-life is expected to vary from patient to patient.)	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	22-25 days following IM administration	Mean values between 17.5 and 25 days (range 5.9 - 35 days)	23.1 ± 5.5 days
Storage Requirements	Store VARIZIG at 2 to 8°C (36 to 46°F). Do not freeze. Do not use after expiration date	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.	Refrigeration 2°-8°C (36°-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.
Shelf Life from Date of Manufacture	36 months	36 months	36 months	36 months	36 months - must use by expiration date on vial	36 months	36 months	39 months
Available Sizes	Single-dose vial: 3 mL	Preservative (thimerosol)-free, latex-free single dose vials: 2 mL, 10 mL	Preservative (thimerosol)-free, prefilled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system: 250 unit prefilled disposable syringe	Preservative (thimerosol)-free, latex-free single dose vials: 2 mL, 10 mL	Single Vial: 2 mL vial	Single-dose vial: 1 mL, 5 mL	* 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: 1 mL, 5 mL