# Hyper-Immune Products



| Product Specifics | IMIG | | Hepatitis B | | Rabies | | Tetanus |
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| | **GamaSTAN® S/D**<br>Grifols | **VARIZIG**<br>Saol Therapeutics | **HepaGam B**<br>Saol Therapeutics | **HyperHEP B® S/D**<br>Grifols | **HyperRAB® S/D**<br>Grifols | **KEDRAB®**<br>Kedrion | **HyperTET® S/D**<br>Grifols |
| **Indications** | Hepatitis A post-exposure prophylaxis, rubeola, rubella, varicella | Indicated for post-exposure prophylaxis in high risk individuals (1). High risk groups include:<br>· immunocompromised children and adults,<br>· newborns of mothers with varicella shortly before or after delivery,<br>· premature infants,<br>· infants less than one year of age,<br>· adults without evidence of immunity,<br>· pregnant women.<br>VARIZIG administration is intended to reduce the severity of varicella. | 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 | Rabies vaccine and HyperRAB S/D should be given to all persons suspected of exposure to rabies with one exception: persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer should receive only vaccine. HyperRAB S/D should be administered as promptly as possible after exposure, but can be administered up to the eighth day after the first dose of vaccine is given. | KEDRAB is a human rabies immunoglobulin (HRIG) indicated for passive, transient post-exposure prophylaxis of rabies infection, when given immediately after contact with a rabid or possibly rabid animal. KEDRAB should be administered concurrently with a full course of rabies vaccine. | Prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain. Also indicated in the regimen of treatment of active cases of tetanus. |
| **Contraindications** | Do not give GamaSTAN S/D to persons with isolated immunoglobulin A (IgA) deficiency. Such persons have the potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.<br>Do not give GamaSTAN S/D to patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. | · Individuals known to have anaphylactic or severe systemic (hypersensitivity) reactions to human immune globulin preparations should not receive VARIZIG.<br>· IgA-deficient patients with antibodies against IgA and a history of hypersensitivity may have an anaphylactoid reaction.<br>· VARIZIG contains less than 40 micrograms per milliliter of 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 anaphylactoid 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. | 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 | 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. |
| **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. Manufacturing process includes steps that provide significant removal (≥ 6.7 log10) of TSE infectivity. | 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. | 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 contributes 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. | 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 manufacturing process for KEDRAB includes three steps specifically designed to remove or inactivate viruses. The first of these is solvent/detergent (S/D) treatment with a mixture of tri-(n-butyl) phosphate (TnBP) and Octynoxol 9, which inactivates enveloped viral agents such as HIV, HBV and HCV. The second and third are heat-treatment (pasteurization) steps, which can inactivate both enveloped and non–enveloped viruses, and a nanofiltration (NF) step which removes viruses on the basis of size | 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. |
| **Route of Administration** | Intramuscular | For intramuscular administration only | 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 | If anatomically feasible, up to the full dose of HyperRAB S/D should be thoroughly infiltrated in the area around the wound and the rest should be administered intramuscularly in the deltoid muscle of the upper arm or lateral thigh muscle. The gluteal region should not be used as an injection site because of the risk of injury to the sciatic nerve. [26] HyperRAB S/D should never be administered in the same syringe or needle or in the same anatomical site as vaccine. | Wound infiltration and intramuscular use. Infiltrate as much of the dose as possible into and around any detectable bite wounds. Inject any remaining volume intramuscularly into the upper arm deltoid region or, in small children, into the anterolateral aspect of the thigh. Administer the remaining KEDRAB at site(s) distant from the site of the rabies vaccine. | Intramuscular |
| **Potency** | Varies according to indication for use. Contact Grifols Medical Information at 1-800-520-2807 if you have specific potency questions. | Each vial of VARIZIG contains a minimum potency of 125 IU in 1.2 mL. | A minimum potency of > 312 IU/mL. The measured potency of each lot is also stamped on the vial label. A potency of 550 IU/mL is targeted at the time of manufacture. | Minimum 220 IU/mL | Average 150 IU/mL | Nominal potency of 150 IU/mL | Minimum of 250 AU (anti-toxin units)/syringe |
| **Protein Concentration** | 15 - 18% protein solution | 6-13% protein solution | 5% | 15 - 18% protein solution | 15 - 18% protein solution | ≥95% IgG protein | 15 - 18% protein solution |
| **Product Half Life** | The half-life of IgG in the circulation of individuals with normal IgG levels is 23 Days | 26.2 ± 4.6 days (The half-life is expected to vary from patient to patient.) | 22-25 days following IM administration | Mean values between 17.5 and 25 days (range 5.9 - 35 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. | Approximately 17.9 days | The half-life of IgG in the circulation of individuals with normal IgG levels is 23 Days |
| **Storage Requirements** | 2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used. | Store VARIZIG at 2 to 8°C (36 to 46°F). Do not freeze. Do not use after expiration date | 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. | 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. KEDRAB may be stored at room temperatures not exceeding 25 °C (77 °F) for up to one month. Use within one month after removal from refrigeration, Do not return to refrigeration. | 2°-8°C (36°-46°F). Do not freeze. Solution that has been frozen should not be used. |
| **Shelf Life from Date of Manufacture** | 36 months | 36 months | 36 months | 36 months | 36 months | 30 months | 36 months |
| **How Supplied** | Preservative (thimerosol)-free, latex-free single dose vials:<br>2 mL, 10 mL | Single-dose vial: 3 mL | Single-dose vial:<br>1 mL, 5 mL | HyperHEP B S/D is supplied in a 0.5 mL neonatal single dose syringe with attached needle, a 1 mL single dose syringe with attached needle and a 1 mL and a 5 mL single dose vial. HyperHEP B S/D is preservative (thimerosol)-free and latex-free. | Preservative (thimerosol)-free, latex-free single dose vials:<br>2 mL, 10 mL | Preservative free, latex-free, pyrogen free single dose vials:<br>2 mL, 10 mL | Preservative (thimerosol)-free, prefilled disposable syringes with attached UltraSafe® Needle Guard in a latex-free delivery system:<br>250 unit prefilled disposable syringe |