privigen™

Immune Globulin Intravenous (Human), 10% Liquid

IVIg therapy made simple

Advancing Ig therapy. The first and only proline-stabilised 10% liquid human IVIg[1]

85+ Countries[2] | 1,000,000+ Patient-years exposure[3]

- Convenient, ready-to-use 10% liquid IgG[4]
- ≥98% Ig purity—only trace amounts of IgA (≤25 mcg/mL)[4]
- If well-tolerated, the rate of administration may gradually be increased to 4.8 mL/kg bw/hour[4]
- Multiple indications: PID, SID, CIDP, ITP, GBS, MMN, and Kawasaki disease[4]

Before prescribing, please review the approved Hong Kong Package Insert, November 2021

Privigen Human normal immunoglobulin solution for infusion (10%)

Indication: Replacement therapy in adults, and children and adolescents (0-18 years) in: • Primary immunodeficiency syndromes (PID) with impaired antibody production; • Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF)* or serum IgG level of <4 g/l. Immunomodulation in adults, and children and adolescents (0-18 years) in: • Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count; •Guillain-Barré syndrome; • Kawasaki disease(in conjunction with acetylsalicylic acid); • Chronic inflammatory demyelinating polyneuropathy (CIDP). Only limited experience is available of use of intravenous immunoglobulins in children with CIDP; • Multifocal motor neuropathy (MMN). ** PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines.* **Dosage:** In replacement therapy the dose may need to be individualised for each patient depending on the clinical response. *Replacement therapy in primary immunodeficiency (PID) syndromes* The recommended starting dose is 0.4 to 0.8 g/kg body weight (bw) given once, followed by at least 0.2 g/kg bw every 3 to 4 weeks. *Secondary immunodeficiencies* The recommended dose is 0.2 – 0.4g/kg bw every three to four weeks. *Primary immune thrombocytopenia (ITP)* • 0.8 to 1g/kg bw given on day 1; this dose may be repeated once within 3 days, OR •0.4 g/kg bw given daily for 2 to 5 days. *Guillain-Barré syndrome* 0.4 g/kg bw/day over 5 days. Kawasaki disease 2.0 g/kg bw should be administered as a single dose. Patients should receive concomitant treatment with acetylsalicylic acid. *Chronic inflammatory demyelinating polyneuropathy (CIDP)* The recommended starting dose is 2 g/kg bw divided over 2 to 5 consecutive days followed by maintenance doses of 1 g/kg bw over 1 to 2 consecutive days every 3 weeks. *Multifocal Motor Neuropathy (MMN)* Starting dose: 2 g/kg given over 2-5 consecutive days. Maintenance dose: 1 g/kg every 2 to 4 weeks or 2 g/kg every 4 to 8 weeks. **Method of administration:** For intravenous use. Privigen should be infused intravenously at an initial infusion rate of 0.3 ml/kg bw/hr for approximately 30 min. If well tolerated, the rate of administration may gradually be increased to 4.8 ml/kg bw/hr. In PID patients who have tolerated the infusion rate of 4.8 ml/kg bw/hr well, the rate may be further gradually increased to a maximum of 7.2 ml/kg bw/hr. **Contraindications:** Hypersensitivity. Patients with selective IgA deficiency who developed antibodies to IgA. Patients with hyperprolinaemia type I or II. **Precautions:** Not indicated in patients with selective IgA deficiency where the IgA deficiency is the only abnormality of concern. Caution for hypersensitivity, haemolytic anaemia, aseptic meningitis syndrome, thromboembolism, acute renal failure, pulmonary adverse reactions, interference with serological testing, possibility of transmissible agents. In case of adverse reaction, IVIg products should be administered at the minimum rate of infusion and dose practicable. Privigen does not contain sucrose, maltose or glucose. Privigen contains less than 2.3 mg sodium per 100 ml. **Undesirable effects:** Headache, pain, pyrexia, influenza like illness, anaemia, haemolysis β, leukopenia, hypersensitivity, dizziness, hypertension, flushing, hypotension, dyspnoea, nausea, vomiting, diarrhoea, abdominal pain, hyperbilirubinaemia, skin disorder, myalgia, fatigue, asthenia, decreased haemoglobin, Coombs`(direct) test positive, increased alanine aminotransferase, increased aspartate aminotransferase, increased blood lactate dehydrogenase. **Date of last revision of PI:** Nov 2021

References

1. *Morio T, et al. Immunological Medicine 2019; 42:4, 162-168* ***2.*** *Data on file. Available from CSL Behring as DOF-PRI-10019.* ***3.*** *Data on file. Available from CSL Behring as DOF-PRI-10020.* ***4.*** *Hong Kong Privigen Package Insert, Nov 2021*

Ig: immunoglobulin; IVIg: intravenous immunoglobulin; bw: body weight; PID: Primary immunodeficiency syndromes; SID: Secondary immunodeficiencies; CIDP: Chronic inflammatory demyelinating polyneuropathy; ITP: Primary immune thrombocytopenia; GBS: Guillain-Barré syndrome; MMN: Multifocal Motor Neuropathy

Biotherapies for Life™ **CSL Behring**

CSL Behring Asia Pacific Limited
4205 - 4208, AIA Tower, 183 Electric Road
North Point, Hong Kong
HKG-PVG-11220008
Date of preparation: Nov 2022