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Privigen® Fact Sheet

(Immune Globulin Intravenous [Human], 10% solution for infusion)

Product Description

Privigen®, an Immune Globulin Intravenous (Human) 10% solution for infusion, uses L-proline as a single stabilizer and offers a simple yet sophisticated choice for healthcare professionals and patients. This formulation makes Privigen® more stable and allows it to be stored either refrigerated or at room temperature[1] for its entire shelf life. Room temperature storage of Privigen® eliminates the need for special refrigerated storage facilities, allows for immediate infusion without the need to warm the IVIG for infusion and most importantly helps reduce wasting of product when a warmed-up product is uselessly discarded if an infusion can not be performed as planned.

Privigen® is also manufactured with Canadian plasma and has labeling and packaging (50mL, 100mL and 200mL vials) that is identical to the US sourced plasma Privigen®.[1]

Indications

Privigen® is indicated for the treatment of patients with primary immunodeficiency (PID), secondary immune deficiency (SID) and immune thrombocytopenic purpura (ITP).[2]

Mechanism of Action

In patients with PID and SID, Privigen® works to replace the antibodies that are either missing or non-functioning and helps to protect the body against infections. Through infusions once every three-to-four weeks, Privigen® can restore low immune globulin (IgG) levels to the normal range.

For chronic ITP, daily infusions of Privigen® can help raise platelet levels to prevent bleeding.[2]

Method of Administration

Privigen® is administered intravenously. The dose and frequency is adjusted according to the type of disease.

If large doses of Privigen® are to be administered, several vials may be pooled using aseptic technique. Because the solution contains no preservative, partially used product should be discarded after 24 hours.

Privigen® is supplied in ready-to-use, single-use vials containing 10g IgG per 100mL (10% liquid).[2]

Clinical Overview

A clinical study of 80 patients with PID treated every three to four weeks with Privigen® for 12 months showed a rate of serious bacterial infections of 0.08 which met the FDA requirement of less than one acute serious bacterial infection (aSBI) per subject.

An additional clinical study conducted in 57 patients with chronic ITP treated daily with two infusions of Privigen® found that Privigen® rapidly raises platelet counts.[2]

Safety Profile

Privigen® is contraindicated in individuals with known anti-IgA antibodies, in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin, and in patients with hyperprolinemia.

During the clinical trial the related temporally associated adverse events in >5% of subjects with PID during or within 72 hours after the end of a Privigen® infusion were headache, nausea, fatigue, chills and pain.

During the clinical trial temporally associated adverse events in >5% subjects with ITP during or within 72 hours after the end of treatment cycle with Privigen® were headache, pyrexia, nausea, vomiting, epistaxis, hyperthermia, bilirubin conjugated increased, blood bilirubin unconjugated increased, hyperbilirubinemia and hematocrit decreased.[2]

For complete risk / benefit profile as well as the full prescribing information of Privigen®, please refer to the current Product Monograph / Prescribing Information, available on our website at www.cslbehring.ca.

References
[1] CSL Behring: Data on file.
[2] Privigen® Product Monograph July 10, 2009, CSL Behring Canada, Inc.