| | |
|---|---|
| **Other Names** | • Hizentra |
| **Description** | • A sterile, liquid, polyvalent human normal immunoglobulin G (IgG) for subcutaneous infusion.<br>• Viral reduction steps include octanoic acid fractionation combined with a filter aid-assisted depth filtration, virus filtration and inactivation by pH 4 incubation as well as additional depth filtration.<br>• Contains at least 98% IgG<br>• IgA content:<br>  ○ Specification: Less than 0.05g/L<br>• Contains L-proline (nonmedicinal clinically relevant ingredient)<br>• Latex-free |
| **Special Approvals/Authorizations** | • An independent 2 person check is required for all doses, as per current standards.<br>• Approval for the product must be obtained by consult with Dr. C. Kalicinsky or immunologist on call. |
| **Classification / Indications** | • Treatment of patients with primary immune deficiency (PID) and Secondary Immune Deficiency (SID) who require immune globulin replacement therapy.<br>• Pregnant women: The safety of Hizentra for use in human pregnancy has not been established in controlled clinical trials. Hizentra should be given to pregnant women only if clearly needed.<br>• Nursing women: Hizentra has not been evaluated in nursing mothers.<br>• Pediatrics (< 18 years of age): Hizentra was not evaluated in neonates or infants.<br>• Geriatrics (> 65 years of age): No specific precautions. |
| **Contraindications** | • In patients with hyperprolinemia as it contains the stabilizer L-proline.<br>• In patients who have had an anaphylactic or severe systemic reaction to the administration of human normal immunoglobulin or to components of.<br>• Warnings:<br>  ○ Do not administer intravenously.<br>  ○ Patients who have not received a preparation of immune globulin before or in the past 8 weeks may be at greater risk of developing fever, chills, nausea, and vomiting. These patients should be monitored closely. On rare occasions, these reactions may lead to shock.<br>  ○ Rarely, can induce a fall in blood pressure with anaphylactic reaction even in patients who had tolerated previous treatment. If anaphylactic reactions are suspected, discontinue administration immediately and contact physician.<br>  ○ Individuals with IgA deficiency can develop anti-IgA antibodies and in very rare cases develop potentially severe hypersensitivity and anaphylactic reactions after administrations of blood components containing IgA. Contains an average of 8mg/L of IgA.<br>  ○ Post marketing reports for immune globulin products has been associated with rare serious thrombotic events including deep venous thrombosis, pulmonary embolism and stroke. Other adverse reactions identified and reported: ARDS, TRALI, aseptic meningitis, Stevens-Johnson syndrome, pancytopenia, hepatic dysfunction, renal impairment. |
| **Supplied** | Available in 5, 10, 20mL single-use vial sizes at a concentration of 0.2 gram/mL (20%). |
| **Dosage** | Usual: 0.1 to 0.2 g/kg weekly in divided doses by push method or via pump using multiple sites.<br>Adjust dose based on clinical response and serum IgG levels.<br>Maximum weekly dose: 0.1-0.2g/kg (weekly), 0.4-0.8g/kg (monthly). If a loading is required, 0.2-0.5g/kg may be given. |

| | |
|---|---|
| **Reconstitution/Stability** | **Reconstitution**<br>• Available as single use vials, 0.2g/ml (20%)<br>**Stability**<br>• Can be stored either in the refrigerator or at room temperature in clean dry place, up to 25°C (77°F)<br>• Do not freeze<br>• Keep Hizentra in its original carton to protect from light<br>• Hizentra is stable for the period indicated by the expiration date printed on the outer carton and vial label.<br>• Do not shake<br>• Discard unused portions immediately after use<br>• **NOT FOR IV USE** |
| **Compatibilities/ Incompatibilities** | • Should not be mixed with other products |
| **Administration, Identification** | Refer to **Manitoba Best Practice Guidelines**<br>• section 2.2 Standards- Identification and Administration |
| **Administration, Method** | • Administer subcutaneously undiluted via push or pump method<br>• Administer 1 ml/min up to 15 mL per injection site for first transfusion<br>• Maximum Rate: May increase to 20 ml per injection site after fourth infusion to a max of 25 ml per injection site<br>• May require up to 4 injection sites<br>• Do not exceed 4 injections sites<br>• Injection sites should be at least 2 inches apart |
| **Adverse Events** | Refer to **Manitoba Best Practice Guidelines** section 2.7 for transfusion reactions. |
| **Resources:** | For further information refer to the Hizentra product monograph at http://www.cslbehring.ca/docs/780/62/2015-12-03_187386_En_Hizentra_PM.pdf |