Immunoglobulin SC, Hizentra®

Hizentra® dosing is weight based; ensure accuracy of documented weight before administration		
Caution High Risk rating		
Form	Hizentra 200 mg/ml solution for subcutaneous injection	Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the vials in the outer carton in order to protect from light.
	Each vial of 5 ml solution contains: 1 g of human normal immunoglobulin Each vial of 10 ml solution contains: 2 g of human normal immunoglobulin Each vial of 20 ml solution contains: 4 g of human normal immunoglobulin Each vial of 50 ml solution contains: 10 g of human normal immunoglobulin	
Reconstitution	Because the solution contains no preservative, Hizentra should be used/infused as soon as possible after opening the vial or blistered pre-filled syringe. The medicinal product should be brought to room or body temperature before use.	
Compatibility & Stability	The solution should be clear and pale-yellow or light-brown. Solutions that are cloudy or have deposits should not be used	
Administration	**Subcutaneous Infusion**	
	Sub cutaneous via specific infusion pump, multiple sites can be used • Refer to SPC for recommended infusion rates	
Monitoring	Ensure that patients are carefully monitored for any symptoms throughout the infusion period. In particular, patients naive to human normal immunoglobulin, patients switched from an alternative immunoglobulin product or when there has been a long interval since the previous infusion should be monitored during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs. All other patients should be observed for at least 20 minutes after the administration	
Documentation Requirements	Document batch numbers and expiry dates of vials in medical notes.	
Adverse Drug Reactions	If Hizentra® is accidentally administered into a blood vessel, patients could develop shock. In case of adverse reaction, either the rate of administration must be reduced or the infusion stopped.	
Additional Information	A number of infusions are carried out in the infusion unit to assess patient suitability for home therapy **Hypersensitivity True allergic reactions** are rare. They can particularly occur in patients with anti-IgA antibodies who should	

	be treated with particular caution. Patients with anti-IgA antibodies, in whom treatment with subcutaneous IgG products remains the only option, should be switched to Hizentra only under close medical supervision. 6 Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin. **Thromboembolism** Arterial and venous thromboembolic events including myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism have been associated with the use of immunoglobulins. Caution should be exercised in patients with pre-existing risk factors for thrombotic events (such as advanced age, hypertension, diabetes mellitus and a history of vascular disease or thrombotic episodes, patients with acquired or inherited thrombophilic disorders, patients with prolonged periods of immobilization, severely hypovolemic patients, patients with diseases which increase blood viscosity). Patients should be informed about first symptoms of thromboembolic events including shortness of breath, pain and swelling of a limb, focal neurological deficits and chest pain and should be advised to contact their physician immediately upon onset of symptoms. Patients should be sufficiently hydrated before use of immunoglobulins. **Aseptic Meningitis Syndrome (AMS)** AMS has been reported with use of IVIg or SCIg. The syndrome usually begins within several hours to 2 days following immune globulin treatment. AMS is characterised by the following signs and symptoms: severe headache, neck stiffness, drowsiness, fever, photophobia, nausea, and vomiting. Patients exhibiting signs and symptoms of AMS should receive a thorough neurological examination, including CSF studies, to rule out other causes of meningitis. Discontinuation of immunoglobulin treatment may result in remission of AMS within several days without sequelae.

Information provided relates to Hizentra® (CSL Behring GmbH)