For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Cerezyme® Injection400 Units (Imiglucerase for injection)
Powder for Concentrate for Solution for Infusion
COMPOSITION: Each vial contains Cerezyme 400 U of imiglucerase and the following excipients: mannitol, sodium citrate, citric acid monohydrate and polysorbate 80. Each vial contains 41 mg of sodium.
THERAPEUTIC INDICATION: Cerezyme® (imiglucerase for injection) is indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease who exhibit clinically significant non-neurological manifestations of the disease.
DOSAGE & ADMINISTRATION: Therapy should be directed by physicians knowledgeable in the management of Gaucher disease. Initial doses of 60 U/kg of body weight once every 2 weeks have shown improvement in haematological and visceral parameters within 6 months of therapy and continued use has either stopped progression of or improved bone disease. The reconstituted and diluted preparation is administered by intravenous infusion over 1 to 2 hours. **Paediatric population:** No dose adjustment is necessary for the paediatric population.
Method of Administration: After reconstitution and dilution, the preparation is administered by intravenous infusion. At initial infusions, Cerezyme should be administered at a rate not exceeding 0.5 unit per kg body weight per minute. At subsequent administrations, infusion rate may be increased but should not exceed 1 unit per kg body weight per minute. Infusion of Cerezyme at home may be considered for patients who are tolerating their infusions well for several months. Decision to have patient move to home infusion should be made after evaluation and recommendation by the treating physician.
SAFETY RELATED INFORMATION
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Warnings & Precautions:
Hypersensitivity/Anaphylactic reactions: As with any intravenous protein product, severe allergic-type hypersensitivity reactions are possible, but occur uncommonly. If these reactions occur, immediate discontinuation of the Cerezyme infusion is recommended and appropriate medical treatment should be initiated. The current medical standards for emergency treatment of anaphylactic reactions are to be observed. Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions
Infusion Associated Reactions: Patients may develop infusion associated reactions (IARs). IARs are defined as any related adverse event occurring during the infusion or during the hours following infusion.
Pregnancy: Limited experience from 150 pregnancy outcomes (primarily based on spontaneous reporting and literature review) is available suggesting that use of Cerezyme is beneficial to control the underlying Gaucher disease in pregnancy. Furthermore, these data indicate no malformative toxicity for the foetus by Cerezyme, although the statistical evidence is low. Treatment naïve women should be advised to consider commencing therapy prior to conception in order to attain optimal health. In women receiving Cerezyme treatment continuation throughout pregnancy should be considered. .
Lactation: It is not known whether this active substance is excreted in human milk, however, the enzyme is likely to be digested in the child's gastrointestinal tract.
ADVERSE REACTIONS: Most common adverse drug reactions are –Dyspnoea, Coughing, Hypersensitivity reactions, urticaria/angioedema, pruritus and rash.

For full prescribing information please contact: Sanofi Healthcare India Pvt Ltd,Sanofi House, CT Survey No 117-B, L& T Business Park, Saki Vihar Road, Powai, Mumbai-400072
Source: EU Summary of Product Characteristics (SmPC) dated Apr 2023
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