Cerezyme®- Abbreviated Summary of Product Characteristics

Cerezyme® 400 U nits/ Vial: powder for concentrate for solution for infusion (imiglucerase). **Product composition**: Each vial of Cerezyme contains 400 U of imiglucerase, a modified form of human acid ß-glucosidase, and the following excipients: mannitol, sodium citrate, citric acid monohydrate and polysorbate 80.Cerezyme contains sodium and is administered in 0.9% sodium chloride intravenous solution. **Indications:** Cerezyme is indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of nonneuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease who exhibit clinically significant nonneuronological manifestations of the disease. The non-neurological manifestations of Gaucher disease include one or more of the following conditions: 1) Anaemia after exclusion of other causes, such as iron deficiency 2) Thrombocytopenia 3) Bone disease after exclusion of other causes such as Vitamin D deficiency 4) Hepatomegaly or splenomegaly. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Dosage and administration:** Disease management should be directed by physicians knowledgeable in the treatment 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. Administration of doses as low as 15 U/kg of body weight once every 2 weeks has been shown to improve haematological parameters and organomegaly, but not bone parameters. The usual frequency of infusion is once every 2 weeks; this is the frequency of infusion for which the most data are available. No dose adjustment is necessary for the paediatric population. 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 rate increases should occur under supervision of a healthcare professional. It is recommended to administer the diluted solution through an in-line low protein-binding 0.2 µm filter to remove any protein particles. **Precautions:** Hypersensitivity: Current data using screening ELISA followed by a confirmatory radioimmunoprecipitation assay suggest that, during the first year of therapy IgG antibodies to imiglucerase are formed in approximately 15% of the treated patients. It appears that patients who will develop IgG antibody are most likely to do so within 6 months of treatment and will rarely develop antibodies to Cerezyme after 12 months of therapy. Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions. Interaction: No interaction studies have been performed. Pregnancy and lactation: Limited experience from 150 pregnancy outcomes is available, suggesting that Cerezyme is beneficial to control the underlying Gaucher disease in pregnancy. These data indicate no malformative toxicity for the foetus. 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. Close monitoring of the pregnancy and clinical manifestations of Gaucher disease is necessary for the individualization of dose according to the patient's needs and therapeutic response. It is not known if Cerezyme is excreted in human milk, however, the enzyme is likely to be digested in the child's gastrointestinal tract. **Adverse drug reactions:** *Common* (≥1/100 to <1/10): dyspnea*, coughing*, hypersensitivity reactions, urticarial/angioedema*, pruritus*, rash*. *Uncommon* (≥1/1,000 to <1/100): headache, dizziness, paraesthesia*, tachycardia*, cyanosis, flushing*, hypotension*, nausea, vomiting, abdominal cramping, diarrhoea, arthralgia, backache*, infusion site discomfort, infusion site burning, infusion site swelling, injection site sterile abscess, chest discomfort*, fever, rigors and fatigue. *Rare* (≥1/10,000 to <1/1,000): anaphylactoid reactions. Symptoms suggestive of hypersensitivity (* marked) have been noted in approximately 3% of the patients. **Overdose:** No case of overdose has been reported. In patients dosages up to 240U/kg body weight once every 2 weeks have been used. **Special precautions for storage:** Store in a refrigerator (2°C – 8°C). Diluted solution: From a microbiological safety point of view, the product should be used immediately. If not used immediately, in-use storage and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2°C - 8°C under protection from light. Revision date: May 2023.

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