Prescribing Information: Cerezyme® (imiglucerase) 400 Units powder for concentrate for solution for infusion

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Each vial of Cerezyme contains 400 U of the active substance imiglucerase. Following reconstitution, the solution contains 40 units (approximately 1 mg) of imiglucerase per ml. Each vial must be further diluted before use (please refer to SmPC for more instructions on dilutions).

Indications: 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. The non-neurological manifestations of Gaucher disease include one or more of the following conditions: anaemia after exclusion of other causes, such as iron deficiency; thrombocytopenia; bone disease after exclusion of other causes such as Vitamin D deficiency; hepatomegaly or splenomegaly.

Dosage and administration: Disease management should be directed by physicians knowledgeable in the treatment of Gaucher disease. Dosage should be individualised for each patient based on a comprehensive evaluation of the clinical manifestations of the disease and individual treatment goals. A range of dosage regimens have proven effective towards some or all non-neurological manifestations. 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. After reconstitution and dilution, the preparation is administered by intravenous (IV) infusion at a usual frequency of infusion is once every 2 weeks. At initial infusions, Cerezyme should be administered at a rate ≤0.5 U/kg body weight per minute. Subsequent administrations, the infusion rate may be increased ≤1 U/kg body weight per minute. Infusion rate increases should always occur under supervision of a healthcare professional. Home infusion: Infusion of Cerezyme at home may be considered for patients who are tolerating their infusions well for several months. This decision should be made after evaluation and recommendation by the treating physician and the patient or caregiver must receive training by a healthcare professional in a clinical setting on how to carry out infusions. The patient or caregiver will be instructed in infusion technique and the keeping of a treatment diary. Patients experiencing adverse events during the infusion must immediately stop the infusion process and seek the attention of a healthcare professional. Subsequent infusions may need to occur in a clinical setting. Dose and infusion rate should remain constant while at home, and not be changed without supervision of a healthcare professional. Medical or healthcare professionals are encouraged to register Gaucher patients, including those with chronic neuronopathic manifestations of the disease, in the "ICGG Gaucher Registry".

Special populations: No dose adjustment is necessary for the paediatric population. The efficacy of Cerezyme on neurological symptoms of chronic neuronopathic Gaucher patients has not been established and no special dosage regimen can be recommended.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: Hypersensitivity: Approximately 15% of the treated patients develop IgG antibodies to imiglucerase within the first year of treatment. It appears that patients who will develop these antibodies are most likely to do so within 6 months of treatment and rarely after 12 months. Patients suspected of a decreased response to the treatment should be monitored periodically for IgG antibody formation to imiglucerase. Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions. If a reaction suggestive of hypersensitivity appears, subsequent testing for imiglucerase antibodies is advised. 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 and the current medical standards for emergency treatment are to be observed. Patients who have developed antibodies or symptoms of hypersensitivity to Ceredase (alglucerase) should be treated with caution when administering Cerezyme. Infusion Associated Reactions (IARs): such as angioedema, pruritus, rash, urticaria, chest discomfort, chills, fatigue, infusion-site burning, infusion-site discomfort, infusion-site swelling, pyrexia and transient hypertension have been observed in patients treated with imiglucerase. Careful consideration should be given to the patient's clinical status prior to administration of Cerezyme. Antihistamines, antipyretics, and/or corticosteroids can be given to prevent or reduce IARs. However, IARs may still occur in patients after receiving pre-treatment. If mild or moderate IARs occur regardless of pre-treatment, decreasing the infusion rate or temporarily stopping the infusion may ameliorate the symptoms. If severe IARs occur, immediate discontinuation of the administration of Cerezyme should be considered and appropriate medical treatment should be initiated. The benefits and risks of re-administering Cerezyme following severe IARs should be considered. Excipients of known effect: This medicinal product contains 41 mg sodium per vial and is administered in 0.9% sodium chloride IV solution, which is to be taken into consideration by patients on a controlled sodium diet.

Interactions: No interaction studies have been performed.

Fertility, pregnancy and lactation: Limited experience (150 pregnancy outcomes) suggests that use of Cerezyme is beneficial to control the underlying Gaucher disease in pregnancy. These data indicate no malformative toxicity for the foetus by Cerezyme, although the statistical evidence is low. Foetal demise has been reported rarely, although it is not clear whether this related to the use of Cerezyme or to the underlying Gaucher disease. It is not known whether Cerezyme passes via the placenta to the developing foetus. In pregnancy and those intending to become pregnant, a risk-benefit treatment assessment is required. Patients who have Gaucher disease and become pregnant may experience a period of increased disease activity during pregnancy and the puerperium. This includes an increased risk of skeletal manifestations, exacerbation of cytopenia, haemorrhage, and an increased need for transfusion. Both pregnancy and lactation are known to stress maternal calcium homeostasis and to accelerate bone turnover. This may contribute to skeletal disease burden in Gaucher disease. 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 whether Cerezyme is excreted in human milk, however if so the enzyme is likely to be digested in the child's gastrointestinal tract.

Adverse Reactions: Adverse effects: *Common:* Dyspnoea, coughing, hypersensitivity reactions, urticaria/angioedema, pruritus, rash. Prescribers should consult the SPC in relation to other adverse reactions.

Legal category: POM.

List Price: £1071.29 x 1 vial.

Marketing Authorisation Number: PLGB 04425/0764.

Marketing Authorisation Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.

Further information is available from: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to uk-drugsafety@sanofi.com