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

Abridged Prescribing Information

MYOZYME®

Alglucosidase alfa for injection (r-DNA origin) 50mg

Lyophilized Powder for concentrate for solution for infusion

COMPOSITION

Each vial contains alglucosidase alfa 50 mg lyophilized powder for concentrate for solution for infusion). After reconstitution, the solution contains 5 mg of alglucosidase alfa per ml and after dilution, the concentration varies from 0.5 mg to 4 mg/ml.

Alglucosidase alfa is a recombinant form of human acid α-glucosidase and is produced in Chinese hamster ovary cells (CHO) by recombinant DNA technology.

THERAPEUTIC INDICATION: Myozyme is indicated for long-term enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of Pompe disease (acid α-glucosidase deficiency).

DOSAGE & ADMINISTRATION: The recommended dose regimen of alglucosidase alfa is 20 mg/kg of body weight administered as intravenous infusion once every 2 weeks. Myozyme has to be reconstituted with water for injections, then diluted with sodium chloride 9 mg/ml (0.9%) solution for injection and then administered by intravenous infusion using aseptic techniques. A 0.2 micron low protein binding in-line filter should be used for administration. Infusions should be administered incrementally. It is recommended that the infusion begin at an initial rate of 1 mg/kg/h and be gradually increased by 2 mg/kg/h every 30 minutes if there are no signs of infusion associated reactions (IARs) until a maximum rate of 7 mg/kg/h is reached.

SAFETY RELATED INFORMATION

Contraindications: Life threatening hypersensitivity (anaphylactic reaction) to the active substance or to any of the excipients, when rechallenge was unsuccessful.

Warnings & Precautions:

Hypersensitivity/Anaphylactic reactions: Serious and life-threatening anaphylactic reactions, including anaphylactic shock, have been reported in infantile- and late-onset patients during Myozyme infusions. The current medical standards for emergency treatment of anaphylactic reactions are to be observed.

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. Patients with an acute illness (e.g. pneumonia, sepsis) at the time of Myozyme infusion appear to be at greater risk for IARs.

Immunogenicity: Patients who experience hypersensitivity reactions may also be tested for IgE antibodies to alglucosidase alfa and other mediators of anaphylaxis. Patients who develop IgE antibodies to alglucosidase alfa appear to be at a higher risk for the occurrence of IARs when Myozyme is re-administered

Immune-mediated reactions: Patients should be monitored for signs and symptoms of systemic immune-mediated reactions involving skin and other organs while receiving alglucosidase alfa.

Immunomodulation: Patients with Pompe disease are at risk of respiratory infections due to the progressive effects of the disease on the respiratory muscles. Therefore, treating patients with Pompe disease with immunosuppressive agents may further increase the risk of developing severe respiratory infections and vigilance is recommended.

Pregnancy: Myozyme should not be used during pregnancy unless clearly necessary.

Lactation: Alglucosidase alfa may be excreted in breast milk. Because there are no data available on effects in neonates exposed to alglucosidase alfa via breast milk, it is recommended to stop breast-feeding when Myozyme is used.

ADVERSE REACTIONS : Hypersensitivity, Agitation, Tremor, Dizziness, Paraesthesia, Headache, Tachycardia, Cyanosis, Flushing, Hypertension, Pallor, Cough, Throat tightness, Vomiting, Retching, Nausea, Diarrhoea, Urticaria, Rash, Erythema, Rash maculopapular, Rash macular, Rash popular, Pruritus, Hyperhidrosis, Muscle spasms, Muscle twitching, Myalgia, Pyrexia, Irritability, Chills, Chest discomfort, Peripheral oedema, Local swelling, Fatigue, Feeling hot, Chest pain, Face edema, Peripheral coldness, Infusion site pain, Infusion site reaction, Oxygen saturation decreased, Heart rate increased, Blood pressure increased, Body temperature increased.

For full prescribing information please contact: Sanofi-Synthelabo (I) Pvt Ltd, Sanofi House, CT Survey No 117-B, L& T Business Park, Saki Vihar Road, Powai, Mumbai-400072

Source: Myozyme India Prescribing Information dated September 2014

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