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

Abridged Prescribing Information

FABRAZYME®

Agalsidase beta Powder for concentrate for solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 35 mg vial of Fabrazyme® contains 37 mg of agalsidase beta as well as 222 mg mannitol, 20.4 mg sodium phosphate monobasic monohydrate, and 59.2 mg sodium phosphate dibasic heptahydrate. 35 mg (7 mL) may be extracted from the vial. Each 5 mg vial of Fabrazyme® contains 5.5mg Agalsidase beta, mannitol 33 mg, sodium phosphate monobasic monohydrate 3 mg, sodium phosphate dibasic heptahydrate 8.8mg.Nitrogen quantity sufficient.Approximate weight of Lyophilized cake 50.3mg.

THERAPEUTIC INDICATION: Fabrazyme(agalsidase beta) is indicated for the treatment of long term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency)

POSOLOGY AND METHOD OF ADMINISTRATION

The recommended dose of Fabrazyme® is 1.0 mg/kg body weight infused every 2 weeks as an IV infusion. In clinical trials, the initial IV infusion rate was administered at a rate of no more than 0.25 mg/min or 15 mg/hr. The infusion rate may be slowed in the event of infusion-associated reactions. After patient tolerance has been established, the infusion rate may be increased gradually with subsequent infusions, as tolerated. For patients ≥30 kg, after patient tolerance to the infusion is well established, increase the infusion rate in increments of 0.05 to 0.08 mg/min (increments of 3 to 5 mg/hour) with each subsequent infusion. In clinical trials, administration was reduced to 1.5 hours for patients weighing ≥30 kg based on individual patient tolerability. For patients weighing <30 kg, the maximum infusion rate is 0.25 mg/minute (15 mg/hour). Infusion of Fabrazyme® at home may be considered for patients who are tolerating their infusions well. The decision to have a patient move to home infusion should be made after evaluation and recommendation by the treating physician. Patients experiencing adverse events during the home infusion need to immediately stop the infusion process and seek the attention of a healthcare professional.

Overall, the safety and efficacy of Fabrazyme®-treatment administered at 1.0 mg/kg every 2 weeks in children between the ages of 8 and 16 years is consistent with that seen in adults. The safety and efficacy of Fabrazyme® at this dose in patients younger than 8 years of age have not been evaluated. The safety and efficacy of Fabrazyme in patients older than 65 years have not been established. No changes in dose are necessary for patients with renal insufficiency. Studies in patients with hepatic insufficiency have not been performed

SAFETY RELATED INFORMATION

Contraindications: No specified.

Special warnings and precautions for use:

As with any intravenously administered protein product, patients may develop antibodies to the protein and immune- mediated reactions are possible. Most patients develop IgG antibodies to Fabrazyme®. Patients with antibodies to r- hαGAL have a higher risk of infusion-associated reactions

Patients treated with Fabrazyme may develop infusion-associated reactions the majority of which are mild to moderate in intensity. If an infusion-associated reaction occurs during a Fabrazyme infusion, decreasing the infusion rate, temporarily stopping the infusion and/or administration of antipyretics, antihistamines, and/or steroids may ameliorate the symptoms. If severe allergic or anaphylactoid reactions occur, immediate discontinuation of the administration of Fabrazyme and current medical standards for emergency treatment are to be provided. The risks and benefits of re-administering Fabrazyme following a severe hypersensitivity or anaphylactoid reaction should be considered.

Patients who have had a positive skin test or who have tested positive for IgE antibodies to r-hαGAL have been successfully rechallenged with Fabrazyme. The initial rechallenge administration should be at a low dose and a lower infusion rate (1/2 the therapeutic dose (0.5mg/kg) at 1/25 the initial standard recommended rate (0.01mg/min)). Once a patient tolerates the infusion, the dose may be increased to reach the therapeutic dose of 1 mg/kg and the infusion rate may be increased by slowly titrating upwards, as tolerated.

It is suggested that patients be monitored periodically for IgG antibody formation**.**

Pregnancy:

Reproduction studies have been performed in rats at doses up to 10mg/kg/day in the fertility study and 30 mg/kg/day in the embryo-fetal development study. These studies have revealed no evidence of impaired fertility or harm to the fetus due to Fabrazyme. No studies of perinatal toxicity have been performed There are, no adequate and well-controlled studies in pregnant women. However, available data from postmarketing studies with agalsidase beta use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Fabrazyme should be used during pregnancy only if clearly needed.

Labor and Delivery: not specified.

Lactation:

There is limited human data to suggest that Fabrazyme is present in human milk. Available data from a clinical study, global pharmacovigilance database, and published scientific literature is insufficient to determine the effects of the drug on the breastfed infant, or on milk production

Undesirable effects: *Frequently reported adverse reactions***:** Infusion-associated reactions (IARs): These IARs included events of chills, fever (pyrexia/body temperature increased/hyperthermia), temperature change sensation (feeling cold/feeling

hot), nausea, vomiting, hypertension (blood pressure increased), flushing (hot flush), paraesthesia (burning sensation), fatigue (lethargy/malaise/asthenia), pain (pain in extremity), headache, pruritus (pruritus generalized), chest pain (chest discomfort), urticaria, dyspnea (dyspnea exacerbated), dizziness, pallor, somnolence, and tachycardia.

For full prescribing information please contact: Sanofi Healthcare India Private Ltd., Sanofi House, CT Survey No 117-B, L& T Business Park, Saki Vihar Road, Powai, Mumbai-400072

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