Fabrazyme® 35mg powder for concentrate for solution for infusion. Product composition: Each vial of Fabrazyme contains a nominal value of 35 mg of agalsidase beta. After reconstitution with 7.2 ml water for injections, each vial of Fabrazyme contains 5 mg/ml (35 mg/7 ml) of agalsidase beta. The reconstituted solution must be diluted further. Agalsidase beta is a recombinant form of human αgalactosidase A and is produced by recombinant DNA technology using a mammalian Chinese Hamster. Ovary (CHO) cell culture. The amino acid sequence of the recombinant form, as well as the nucleotide sequence which encoded it, are identical to the natural form of αgalactosidase A. **Indication:** Fabrazyme is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency). Fabrazyme is indicated in adults, children and adolescents aged 8 years and older. **Dosage and administration:** Fabrazyme treatment should be supervised by a physician experienced in the management of patients with Fabry disease or other inherited metabolic diseases. The recommended dose of Fabrazyme is 1 mg/kg body weight administered once every 2 weeks as an intravenous infusion. The initial infusion rate should be no more than 0.25 mg/min (15 mg/hour) to minimize the potential occurrence of infusion associated reactions. After patient tolerance is well established, the infusion rate may be increased in increments of 0.05 to 0.083 mg/min (increments of 3 to 5 mg/hr) with each subsequent infusion. No dose adjustment is necessary for patients with renal insufficiency. Studies in patients with hepatic insufficiency have not been performed. The safety and efficacy of Fabrazyme in patients older than 65 years have not been established and no dosage regimen can presently be recommended in these patients. The safety and efficacy of Fabrazyme in children aged 0 to 7 years have not yet been established. Currently available data are described in sections 5.1 and 5.2 of SmPC but no recommendation on posology can be made in children aged 5 to 7 years. No data are available in children 0 to 4 years. No dose adjustment is necessary for children 8-16 years. **Possible side-effects** Adverse reactions reported from clinical trials with a total of 168 patients (154 males and 14 females) treated with Fabrazyme administered at a dose of 1 mg/kg every 2 weeks for a minimum of one infusion up to a maximum of 5 years • Very common (≥ 1/10): headache, paraesthesia, nausea, vomiting, chills, pyrexia, feeling cold. • Common (≥ 1/100 to < 1/10): nasopharyngitis, dizziness, somnolence, hypoaesthesia, burning sensation, lethargy, syncope, lacrimation increased, tinnitus, vertigo, tachycardia, palpitations, bradycardia, flushing, hypertension, pallor, hypotension, hot flush, dyspnoea, nasal congestion, throat tightness, wheezing, cough, dyspnea exacerbated, abdominal pain, abdominal pain upper, abdominal discomfort, stomach discomfort, hypoaesthesia oral, diarrhea, pruritus, urticaria, rash, erythema, pruritus generalized, angioneurotic oedema, swelling face, rash maculo-papular, pain in extremity, myalgia, back pain, muscle spasms, arthralgia, muscle tightness, musculoskeletal stiffness, fatigue, chest discomfort, feeling hot, oedema peripheral, pain, asthenia, chest pain, face oedema, hyperthermia. • Uncommon (≥ 1/1000 to < 1/100): rhinitis, hyperaesthesia, tremor, eye pruritus, ocular hyperaemia, auricular swelling, ear pain, sinus bradycardia, peripheral coldness, bronchospasm, pharyngolaryngeal pain, rhinorrhoea, tachypnoea, upper respiratory tract congestion, dyspepsia, dysphagia, livedo reticularis, rash erythematous, rash pruritic, skin discolouration, skin discomfort, musculoskeletal pain, feeling hot and cold, influenza-like illness, infusion site pain, infusion site reaction, injection site thrombosis, malaise, oedema. Adverse reactions only reported during the Post Marketing period are also included at a frequency category of "not known": anaphylactoid reaction, hypoxia, leukocytoclastic vasculitis, oxygen saturation decreased. **Special warnings and precautions: Immunogenicity** Since agalsidase beta (r-hαGAL) is a recombinant protein, the development of IgG antibodies is expected in patients with little or no residual enzyme activity. The majority of patients developed IgG antibodies to r-hαGAL, typically within 3 months of the first infusion with Fabrazyme. Over time, the majority of seropositive patients in clinical trials demonstrated either a downward trend in titres (based on a ≥ 4-fold reduction in titre from the peak measurement to the last measurement) (40% of the patients), tolerised (no detectable antibodies confirmed by 2 consecutive radioimmuno-precipitation (RIP) assays) (14% of the patients) or demonstrated a plateau (35% of the patients). **Infusion associated reactions:** Patients with antibodies to rhαGAL have a greater potential to experience infusion associated reactions (IARs). **Hypersensitivity** As with any intravenous protein medicinal product, allergic type hypersensitivity reactions are possible. A small number of patients have experienced reactions suggestive of immediate (Type I) hypersensitivity. If severe allergic or anaphylactic type reactions occur, immediate discontinuation of the administration of Fabrazyme should be considered and appropriate treatment initiated. **Pregnancy, lactation and fertility**: There are limited data from the use of agalsidase beta in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Fabrazyme during pregnancy. Agalsidase beta is excreted in human milk. The effect of agalsidase beta on newborns/infants is unknown. Studies have not been conducted to assess the potential effects of Fabrazyme on impairment of fertility. **Contraindications:** Life threatening hypersensitivity (anaphylactic reaction) to the active substance or any of the excipients. Marketing authorization holder: Sanofi B.V., Paasheuvelweg 25, 1105 BP Amsterdam, The Netherlands Manufacturer: Genzyme Ireland Ltd., IDA Industrial Park, Old Kilmeaden Road, Waterford, Ireland
Text revision date: March 2024
To report any adverse event please contact us at: **Levant.Pharmacovigilance@sanofi.com**
For any medical inquiry please contact us at: **Levant.medinfo@sanofi.com**

MAT-IQ-2600095 (v1.0) May 2026