

## **ABBREVIATED PRESCRIBING INFORMATION (REPLAGAL)**

**AGALSIDASE ALFA (r-DNA origin) 1 mg/ml (REPLAGAL™) Concentrate for Solution for Infusion**

**Mechanism of Action:** Agalsidase alfa catalyses the hydrolysis of Gb3, cleaving a terminal galactose residue from the molecule. Treatment with the enzyme has been shown to reduce accumulation of Gb3 in many cell types including endothelial and parenchymal cells.

**Indication and usage:** Replagal™ is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry Disease ( $\alpha$ -galactosidase A deficiency).

**Dosage administration:** Replagal™ is administered at a dose of 0.2 mg/kg body weight every other week by intravenous infusion over 40 minutes.

**Interaction:** Replagal™ should not be co-administered with chloroquine, amiodarone, benoquin or gentamicin since these substances have the potential to inhibit intra-cellular  $\alpha$ -galactosidase activity. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Fertility, Pregnancy and lactation:** It is not known whether Replagal™ is excreted in human milk. No effects on male fertility were seen in reproductive studies in male rats.

**Adverse reactions:** headache, flushing, nausea, rigors, pyrexia, pain, discomfort, fatigue, peripheral oedema, dizziness, dysgeusia, neuropathic pain, tremor, hypersomnia, hypoesthesia, paraesthesia, corneal reflex decreased, lacrimation increased, tinnitus, tinnitus aggravated, tachycardia, palpitations, hypertension, cough, hoarseness, throat tightness, dyspnoea, nasopharyngitis, pharyngitis, throat secretion increased, rhinorrhoea, diarrhoea, vomiting, abdominal pain/discomfort, acne, erythema, pruritus, rash, livedo reticularis, musculoskeletal discomfort, myalgia, back pain, limb pain, peripheral swelling, arthralgia, joint swelling, fatigue aggravated, feeling hot, feeling cold, asthenia, chest pain, chest tightness, influenza like illness, injection site rash, malaise, parosmia, oxygen saturation decreased, angioneurotic oedema, urticaria, sensation of heaviness, Anaphylactic reaction, hypersensitivity, atrial fibrillation, tachyarrhythmia, hypotension, hyperhidrosis.

**Special population:** Studies in patients over the age of 65 and with hepatic impairment have not been performed. No dose adjustment is necessary in patients with renal impairment. The safety and efficacy of Replagal™ in children aged 0-6 years has not yet been established.

**Storage:** Store in a refrigerator (2°C to 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light. For more information refer full prescribing information

**Imported and Marketed By: Takeda Biopharmaceuticals India Private Limited, 6th Floor,  
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**Date of Preparation of the API: May 2024 based on India PI-Date of revision of text: June  
2023. REPLAGAL is a registered trademark of Shire Human Genetic Therapies, Inc.**

PI-03130

**For the use of a registered medical practitioner or a hospital or a laboratory only.**