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

Abridged Prescribing Information

ALDURAZYME®

LARONIDASE FOR SOLUTION FOR INJECTION

Solution for Intravenous Infusion Only

COMPOSITION:ALDURAZYME, for intravenous (IV) infusion, is supplied as a sterile, single-use, colorless solution in a 5ml glass vial containing 2.9 mg laronidase, 43.9 mg sodium chloride, 63.5 mg sodium phosphate monobasic monohydrate, 10.7 mg sodium phosphate dibasic heptahydrate, and 0.05 mg polysorbate 80.

THERAPEUTIC INDICATION:

ALDURAZYME (laronidase) is indicated for patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms.

DOSAGE AND ADMINISTRATION

Each vial of ALDURAZYME is intended for single use only. The recommended dosage regimen of is 0.58 mg/kg of body weight administered once weekly as an intravenous (IV) infusion. Pretreatment is recommended 60 minutes prior to the start of the infusion and may include antihistamines, antipyretics, or both. The concentrated solution for infusion must be diluted with 0.9% Sodium Chloride Injection, USP, to a final volume of 100 mL or 250 mL, using aseptic techniques. The final volume of the infusion is determined by the patient's body weight. Patients with a body weight of 20 kg or less should receive a total volume of 100 mL. Patients with a body weight greater than 20 kg should receive a total volume of 250 mL.The entire infusion volume (100 mL for patients weighing 20 kg or less and 250 mL for patients weighing greater than 20 kg) should be delivered over approximately 3 to 4 hours.

SAFETY RELATED INFORMATION

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Anaphylaxis and Allergic Reactions: Anaphylaxis and severe allergic reactions have been observed in patients during or up to 3 hours after ALDURAZYME infusions.

Acute Respiratory Complications Associated with Administration: Patients with an acute febrile or respiratory illness at the time of ALDURAZYME infusion may be at greater risk for infusion reactions. Evaluation of airway patency should be considered prior to initiation of treatment with ALDURAZYME.

Risk of Acute Cardiorespiratory Failure: Caution should be exercised when administering ALDURAZYME to patients susceptible to fluid overload or patients with acute underlying respiratory illness or compromised cardiac and/or respiratory function for whom fluid restriction is indicated.

Infusion Reactions: Because of the potential for infusion reactions, patients should receive antipyretics and/or antihistamines prior to infusion.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no adequate and well-controlled studies of ALDURAZYME in pregnant women. Aldurazyme should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether the drug is excreted in human milk. Caution should be exercised when ALDURAZYME is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of ALDURAZYME in patients with MPS I, ages 6 months to 5 years old, was found to be similar to the safety and effectiveness of ALDURAZYME in pediatric patients 6 to 18 years and adults .

ADVERSE REACTIONS

The most common adverse reactions with ALDURAZYME were infusion reactions e.g. flushing, pyrexia, headache, and rash. Other reported adverse reactions included bronchospasm, dyspnea, urticaria and pruritus.

Immunogenicity: Potential for antibody neutralization of cellular uptake has not been assessed. As with all the therapeutic proteins, there is potential for immunogenicity.

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: Aldurazyme India Prescribing Information dated June 2016

Date: August 2017