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 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 of is 0.58 mg/kg (actual body weight) administered once weekly as an intravenous infusion. Aldurazyme injection must be diluted with 0.9% Sodium Chloride Injection, to a final volume of 50 mL, 100 mL or 250 mL. as determined by the patient's body weight and cardiopulmonary condition:

. Patients with a body weight equal to or greater than 2 kg and less than 4 kg should receive a total volume of 50 mL. Patients with a body weight equal to or greater than 4 kg and up to 20 kg should receive a total volume of 100 mL; and those 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.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Anaphylaxis and Allergic Reactions: Hypersensitivity reactions including anaphylaxis have been reported in patients during or up to3 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: In postmarketing experience, reports of acute cardiorespiratory failure have been reported with ALDURAZYME treatment. 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-Associated Reactions: Aldurazyme may cause infusion-associated reactions (IARs), Prior to ALDURAZYME administration, consider pre-medicating with antihistamines, with or without antipyretics, 60 minutes before the start of infusion to reduce the risk of IARs

USE IN SPECIAL POPULATIONS

Pregnancy: An MPS I Registry has been established Pregnant women with MPS I and healthcare providers are encouraged to contact the pregnancy sub-registry. Available data from the MPS I Registry pregnancy sub-registry

published case reports and the global pharmacovigilance database with ALDURAZYME use in more than 30 pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation: There are no available data on the presence of laronidase in human milk or the effects on milk production. No adverse effects have been reported in breastfed infants in a few postmarketing cases of laronidase use in lactating women.

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. Serious and or clinically significant adverse reactions include: Anaphylaxis and Hypersensitivity Reactions, Acute Respiratory Complications Associated with Administration, Risk of Acute Cardiorespiratory Failure and Infusion Reactions.

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 Healthcare India Pvt Ltd,, Sanofi House, CT Survey No 117-B, L& T Business Park, Saki Vihar Road, Powai, Mumbai-400072

Source: USPI of Aldurazyme dated December 2023

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