Name: Aldurazyme 100 U/ml concentrate for solution for infusion. **Presentation:** 1ml contains 100U (approximately 0.58mg) of laronidase. Each vial of 5ml contains 500U of laronidase and 1.29mmol sodium. **Indication:** Aldurazyme is indicated for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis I (MPS I; α-L-iduronidase deficiency) to treat the non-neurological manifestations of the disease. **Dosage and administration:** The recommended dosage regimen of Aldurazyme is 100U/kg bodyweight administered once every week as an intravenous (IV) infusion. The initial infusion rate of 2U/kg/h may be incrementally increased every 15 minutes, if tolerated, to a maximum of 43U/kg/h. The total volume of the administration should be delivered in approximately 3-4 hours. **Paediatric:** No dose adjustment necessary. **Elderly (≥65 years):** No data therefore no dosage can be recommended**. Renal and hepatic impairment**: No data therefore no dosage can be recommended. **Contraindications:** Severe hypersensitivity (e.g. anaphylactic reaction) to the active substance or to any of the excipients. **Warnings and Precautions:** Infusion-associated reactions (IARs): Patients treated with Aldurazyme should be closely monitored and all cases of IARs, delayed reactions and possible immunological reactions should be reported. Antibody status should be regularly monitored and reported. Almost all patients are expected to develop IgG antibodies to Aldurazyme, mostly within 3 months of initiation of treatment. Patients who have developed antibodies or symptoms of IARs should be treated with caution. Patients with an acute underlying illness appear to be at greater risk for IARs, thus careful consideration should be given to the patient's clinical status prior to administration. Initial administration of Aldurazyme or upon re-administration (following interruption of treatment) it is recommended that patients be administered pre-treatment medication (antihistamines and/or antipyretics) approximately 60 minutes prior to the infusion, to minimize the potential occurrence of IARs. If clinically indicated, administration of pre-treatment medication with subsequent infusions of Aldurazyme should be considered. In case of a mild or moderate IAR, treatment with antihistamines and paracetamol/ ibuprofen should be considered, and/or a reduction in the infusion rate to half the infusion rate at which the reaction occurred. In case of a single severe IAR, the infusion should be stopped until the symptoms have resolved, and treatment with antihistamines and paracetamol/ ibuprofen should be considered. The infusion can be restarted with a reduction of the infusion rate to 1/2–1/4 the rate of the infusion at which the reaction occurred. In case of a recurrent moderate IAR or re-challenge after a single severe IAR, pre-treatment should be considered (antihistamines and paracetamol or ibuprofen and/or corticosteroids) and a reduction of the infusion rate to 1/2–1/4 the rate of the infusion at which the previous reaction occurred. If these reactions occur, immediate discontinuation of Aldurazyme is recommended and appropriate medical treatment should be initiated. Sodium: This medicinal product contains 30 mg sodium per vial, equivalent to 1.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult and is administered in 0.9% sodium chloride intravenous solution. **Interactions:** No interaction studies have been performed. Aldurazyme is an unlikely candidate for cytochrome P450 mediated interactions. Aldurazyme should not be administered simultaneously with chloroquine or procaine due to a potential risk of interference with the intracellular uptake of Aldurazyme. **Pregnancy:** There are inadequate data on the use of Aldurazyme in pregnant women, thus the potential risk for humans is unknown. Aldurazyme should not be used in pregnancy unless clearly necessary. **Breastfeeding:** Aldurazyme may be excreted in milk. It is recommended to stop breast-feeding during Aldurazyme treatment. **Fertility:** no clinical data. **Adverse effects:** very common (≥1/10)Headache, Flushing, Nausea, abdominal pain, rash, Arthropathy, arthralgia, back pain, pain in extremity, Pyrexia, infusion site reaction; common (≥1/100 to <1/10) Anaphylactic reaction, Restlessness, Paraesthesia, dizziness, Tachycardia, Hypotension, pallor,peripheral coldness, Respiratory distress, dyspnoea, cough, Vomiting, diarrhoea, Angioneurotic edema, swelling face, urticaria, pruritus, cold sweat, alopecia, hyperhidrosis, Musculoskeletal pain, Chills, feeling hot, feeling cold, fatigue, influenza like illness, injection site pain, Body temperature increased, oxygen saturation decreased; not known: Hypersensitivity, Bradycardia, Hypertension, Cyanosis, hypoxia, tachypnoea, bronchospasm, respiratory arrest, laryngeal oedema, respiratory failure, pharyngeal swelling, stridor, obstructive airways disorder, Lip swelling, swollen tongue, Erythema, facial edema, Extravasation, oedema peripheral, Drug specific antibody, neutralizing antibodies, blood pressure increased. **Special precautions** for storage Store in a refrigerator (2°C – 8°C). Diluted solutions: From a microbiological safety point of view, the product should be used immediately. If not used immediately, in-use storage should not be longer than 24 hours at 2°C - 8°C provided that dilution has taken place under controlled and validated aseptic conditions.

MARKETING AUTHORISATION HOLDER Aventis Pharma Limited, 410 Thames Valley Park Drive, UK. Text revision date June 2023

To report an adverse event, please email us at: Levant.Pharmacovigilance@sanofi.com
For any Medical enquiry email us at levant.medinfo@sanofi.com