PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ALDURAZYME®, 500 U/5 mL

concentrate for solution for infusion

Laronidase

Sugar free.

Please read all of this leaflet carefully before using ALDURAZYME.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ALDURAZYME has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ALDURAZYME is and what it is used for

Active ingredient: Each vial of 5 mL contains 500 U (2,9 mg) of laronidase.

1 mL contains 100 U (0,58 mg) of laronidase.

ALDURAZYME is used to treat some of the symptoms of a genetic condition called mucopolysaccharidosis I (MPS I).

It is given to treat the non-neurological manifestations of the disease.

People with MPS I disease have either a low level or none of an enzyme called α-L-iduronidase, which breaks down specific substances (glycosaminoglycans) in the body. As a result, these substances do not get broken down and processed by the body as they should. They accumulate in many tissues in the body, which causes the symptoms of MPS I.

ALDURAZYME is an artificial enzyme called laronidase. This can replace the natural enzyme which is lacking in MPS I disease.

2. What you need to know before you are given ALDURAZYME

ALDURAZYME should not be administered to you:

If you have a severe allergic (hypersensitive) reaction to laronidase or any of the other ingredients of ALDURAZYME (listed in section 6) and these reactions occurred again after stopping and restarting ALDURAZYME.

Warnings and precautions

Take special care with ALDURAZYME:

If you are treated with ALDURAZYME, you may develop infusion-associated reactions. An infusion-associated reaction is any side effect occurring during the infusion or until the end of the infusion day (see section 4 – Possible side effects). Some of these reactions may be severe. When you experience such a reaction, **you should immediately contact your doctor**.

If these reactions occur, the ALDURAZYME infusion should be stopped immediately and appropriate treatment will be started by your doctor. These reactions may be particularly severe if you have a pre-existing MPS I-related upper airway obstruction.

If you suffer from any underlying illness, inform your doctor before you receive ALDURAZYME.

You may be at greater risk of developing an infusion-associated reaction.

If you have any kidney or liver disease, inform your doctor before you receive ALDURAZYME. The safety and efficacy of ALDURAZYME have not been evaluated in patients with kidney or liver disease and no dosage regimen can be recommended in such patients.

Talk to your doctor or pharmacist immediately if treatment with ALDURAZYME causes allergic reactions, including anaphylaxis (a severe allergy reaction), see section 4 – Possible side effects. Some of these reactions may be life-threatening. Symptoms may include respiratory failure/distress (inability of lungs to work properly), stridor (high-pitched breathing sound) and other disorders due to obstruction of airways, rapid breathing, excessive contraction of the airway muscles causing difficulty breathing (bronchospasm), lack of oxygen in body tissues (hypoxia), low blood pressure, slow heart rate or itchy rash (urticaria).

You may be given additional medication such as antihistamines and paracetamol to help prevent allergic-type reactions.

Other medicines and ALDURAZYME:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take medicines containing chloroquine (used to prevent or treat malaria) or procaine (a local anaesthetic used during surgical and dental procedures) at the same time as ALDURAZYME. These medicines may decrease the action of ALDURAZYME.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before

receiving ALDURAZYME.

There is not enough experience of the use of ALDURAZYME in pregnant women. You should not be given ALDURAZYME during pregnancy.

It is not known whether ALDURAZYME appears in breast milk. It is recommended to stop breastfeeding during treatment with ALDURAZYME.

No information is available on the effects of ALDURAZYME on fertility.

Driving and using machines:

The effects of ALDURAZYME on the ability to drive and to use machines have not been studied. Do not drive a vehicle, operate machinery, or do anything else that could be dangerous until you know how ALDURAZYME affects you.

ALDURAZYME contains sodium:

ALDURAZYME contains 1,29 mmol or 30 mg sodium (the main component of cooking/table salt) per vial. This is equivalent to 1,5 % of the recommended maximum daily dietary intake of sodium for an adult. To be taken into consideration by patients on a sodium-controlled diet.

3. How ALDURAZYME is given

Instruction for use - dilution and administration

ALDURAZYME concentrate for solution for infusion has to be diluted before administration and is for intravenous use only.

Administration of ALDURAZYME should be carried out in an appropriate clinical setting where resuscitation equipment to manage medical emergencies would be readily available.

Home infusion

Your doctor may consider that you can have home infusion of ALDURAZYME if it is safe and convenient to do so. If you get a side effect during an infusion of ALDURAZYME, your health care provider may stop the infusion and start appropriate medical treatment.

Dosage

Your doctor will decide on the correct dose of ALDURAZYME to obtain the results needed. The dose of ALDURAZYME will be different in each patient corresponding to your condition and body mass.

The recommended dosage regimen of ALDURAZYME is 100 U/kg body weight given once every week as an intravenous infusion. The initial infusion rate of 2 U/kg/h may be gradually increased every fifteen minutes, if tolerated, to a maximum of 43 U/kg/h. The total volume of the administration should be delivered in approximately 3 – 4 hours.

Always use ALDURAZYME exactly as your doctor has told you. Check with your doctor if you are not sure.

If you receive more ALDURAZYME than you should:

Since your doctor or health care provider will administer ALDURAZYME, he/she will control the dosage. However, in the event of overdosage, your doctor will treat the side effects symptomatically.

If the dose of ALDURAZYME given is too high or the infusion is too fast, adverse drug reactions may occur. Receiving an excessively fast infusion of ALDURAZYME may cause nausea, stomach pain, headache, dizziness and difficulty breathing. In such situations, the infusion must be stopped immediately. Your doctor will decide if further intervention is required.

If you miss an infusion of ALDURAZYME:

Since a health care provider will administer ALDURAZYME, it is unlikely that the dose will be missed.

4. Possible side effects

ALDURAZYME can have side effects.

Not all side effects reported for ALDURAZYME are included in this leaflet. Should your general health worsen or you experience any untoward effects while receiving ALDURAZYME, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving ALDURAZYME and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Yellowing of your skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ALDURAZYME. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Increased heart rate.
- Airway constriction, difficulty in breathing which may be extreme.
- Fast breathing or stopping to breathe (respiratory arrest).
- Shortness of breath.
- Blueish discolouration of skin (due to lower levels of oxygen in your blood).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

The following very common side effects may occur:

- Headache.
- Nausea, stomach pain.

- Joint disease, joint pain, back pain, pain in arms or legs.
- Flushing.
- Fever, chills.
- Increased blood pressure.
- Reaction at the infusion site.

Common side effects include the following:

- Increased body temperature, tingling, dizziness.
- Cough.
- Vomiting, diarrhoea.
- Hair loss, cold sweat, heavy sweating, muscle pain, low blood pressure, paleness, cold hands and/or feet, feeling hot, feeling cold, fatigue.
- Influenza-like illness, allergic reaction, restlessness.
- Redness of your skin.
- Leakage of the medicine into the surrounding tissue at the site of the injection which may cause swelling or redness, pain, rash, build-up of fluid, discomfort, itchy rash, pale colour of the skin, discoloured skin, and sensation of being warm.
- Respiratory failure, inability of lungs to work properly, high pitched breathing sound.
- Antibodies, a blood protein produced in response to medicine.
- Antibodies that neutralises the effect of the medicine.
- Abnormally slower heart rate.
- Swelling of your arms and/or legs.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at

za.drugsafety@sanofi.com (email), https://ae.reporting.sanofi/ (web portal) or +27 11 256 3700 (tel).

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

5. How to store ALDURAZYME

Concentrate (unopened vial):

Store in a refrigerator at 2 °C – 8 °C.

Do not freeze.

DO NOT USE ALDURAZYME after the expiration date on the vial label.

Diluted solution:

The diluted preparation contains no preservatives. This may be used in very young children. Use 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.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ALDURAZYME contains:

Active ingredient: Each vial of 5 mL contains 500 U (2,9 mg) of laronidase.

1 mL contains 100 U (0,58 mg) of laronidase.

Inactive ingredients: Polysorbate 80, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, water for injection.

Each vial of 5 mL contains 1,29 mmol sodium.

What ALDURAZYME looks like and contents of the pack:

A clear to slightly opalescent, and colourless to pale yellow liquid.

5 mL concentrate for solution in a clear, transparent type I glass vial with a grey, siliconised, butyl rubber stopper and an aluminium seal with an orange polypropylene flip-off cap.

Pack size: 1 vial.

Holder of Certificate of Registration:

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