Patient Information Leaflet for ELAPRASE®

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ELAPRASE® 6 mg/3 mL concentrate for solution for infusion

Idursulfase

Sugar free.

Please read this leaflet carefully before receiving ELAPRASE.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ELAPRASE 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 ELAPRASE is and what it is used for

ELAPRASE is used as enzyme replacement therapy to treat children and adults with Hunter syndrome (Mucopolysaccharidosis II). If you suffer from Hunter syndrome, a carbohydrate called glycosaminoglycan which is normally broken down by your body, is not broken down and slowly accumulates in various body organs (spleen, liver, lungs, heart, connective tissues and brain).

This causes cells to function abnormally, thereby causing problems for various organs in your body which can lead to tissue destruction and organ malfunction and failure. ELAPRASE contains an active substance called idursulfase which works by acting as a replacement for the enzyme that is at a low level, thereby breaking down this carbohydrate in affected cells.
Enzyme replacement therapy is usually administered as a long-term treatment.

2. What you need to know before you use ELAPRASE

You should not be given ELAPRASE:

If you have experienced severe or potentially life-threatening allergic-type reactions to idursulfase or to any of the ingredients of ELAPRASE (see section 6).

Warnings and precautions:

Take special care with ELAPRASE:

Inform your health care provider:

If you have severe underlying airway disease.

If you develop rash, itching, hives, fever, headache, high blood pressure and flushing. In the majority of cases, slowing of the infusion-rate has improved these reactions.

If you develop an anaphylactoid/anaphylactic reaction, urgently inform your health care provider, as an anaphylactoid/anaphylactic reaction may be life-threatening.

The nature of your genotype (a genetic make-up of all active genes in human cells, which determines one's specific, individual characteristics) may influence your therapeutic response to

this medicine, as well as your risk of developing antibodies and infusion-related side effects. In individual cases, so-called 'neutralising antibodies' may develop, which may diminish activity of ELAPRASE and your response to treatment. The longer-term effects of antibody development on response to treatment have not been established. Please consult your health care provider for additional information.

Other medicines and ELAPRASE:

Always tell your health care provider if you are taking any other medicine, including complementary or traditional medicines.

No formal interaction studies have been conducted with ELAPRASE.

Pregnancy, breastfeeding and fertility:

The use of ELAPRASE during pregnancy is not recommended.

ELAPRASE may be excreted into breast milk, therefore you should not receive ELAPRASE if you are breastfeeding your baby.

Safety during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, think 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 ELAPRASE.

Driving and using machines:

ELAPRASE may affect your ability to drive and use machines. Take care until you know how ELAPRASE affects your ability to drive or use machines.

ELAPRASE contains sodium:

ELAPRASE contains 11,1 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 0,6 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use ELAPRASE

Your health care provider will administer ELAPRASE to you.

ELAPRASE will be given to you under the supervision of a doctor or nurse who is knowledgeable in the treatment of Hunter syndrome or other inherited metabolic disorders.

The recommended dose is an infusion of 0,5 mg for every kg you weigh. ELAPRASE has to be diluted in sodium chloride 9 mg/mL (0,9 %) solution for infusion before use. After dilution your medicine is given through a vein (drip feed). The infusion will normally last for 1 – 3 hours and be given every week.

Infusion of ELAPRASE at home may be considered for patients who are tolerating their infusions well.

Use in children and adolescents

The recommended dose in children and adolescents is the same as in adults.

If you receive more ELAPRASE than you should

Your doctor will supervise the administration of ELAPRASE and will closely monitor your response and condition and control the dosage. In the unlikely event of overdosage, your doctor will treat the side effects symptomatically. Consult your doctor if you think you have had an overdose of this medicine.

4. Possible side effects

ELAPRASE can have side effects.

Not all side effects reported for ELAPRASE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving ELAPRASE, please consult your health care provider for advice.

If any of the following happens, stop receiving ELAPRASE and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

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

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

Frequent:

- Chest pain.
- Wheezing, difficulty breathing, airway spasms.
- A decrease in oxygen levels in the body (including feeling tired, breathless, light-headed, confused and disorientated).
- Blue or purple discolouration of the skin due to low oxygen levels, also called cyanosis.
- An increase or decrease in blood pressure.
- Changes in the way your heart beats, for example, if you notice it beating faster or abnormally.

Less frequent:

- Rapid breathing.

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

Tell your doctor if you notice any of the following side effects:

Frequent:

- Headache.
- Dizziness, uncontrolled shaking (tremor).
- Flushing (redness of the skin, typically over the cheeks or neck).
- Abdominal pain, nausea, vomiting, diarrhoea, indigestion.
- Swollen tongue.
- Coughing.
- Skin reactions including redness of the skin, rash, hives and itching.
- Joint pain.
- Pain and swelling at injection site.
- Fever.
- Swelling of the face or limbs.

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256 3700 (tel), or
- SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ELAPRASE.

5. How to store ELAPRASE

Store in a refrigerator (2 – 8 °C).

Do not freeze.

For single use only. Discard any unused portion.

Chemical and physical in-use stability has been demonstrated for 8 hours at 25 °C.

After dilution

From a microbiological safety point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 – 8 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ELAPRASE contains:

The active substance is idursulfase, which is a form of the human enzyme iduronate-2-sulfatase.

Each vial of 3 mL contains 6 mg of idursulfase.

Each mL contains 2 mg of idursulfase.

Inactive ingredients:

Polysorbate 20, sodium chloride, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate and water for injection.

What ELAPRASE looks like and contents of the pack:

ELAPRASE is a concentrate for solution for infusion. It is supplied in a glass vial as a clear to slightly opalescent, colourless solution that may have fine particulate matter.

Each vial of ELAPRASE contains 3 mL of concentrate for solution for infusion.

Clear, colourless, type 1 glass 5 mL vial with a fluoro-resin coated butyl rubber stopper, one piece aluminium seal and blue flip-off cap.

Holder of certificate of registration:

sanofi-aventis south africa (pty) ltd

2 Bond Street

Midrand 1685

South Africa

This leaflet was last revised in:

Date of registration: 29 September 2017

Date of revision: 09 November 2021

Registration number:

45/31/0333

INSTRUCTIONS FOR USE:

1. Calculate the total dose to be administered and the number of ELAPRASE vials needed.
2. Dilute the total volume of ELAPRASE concentrate for solution for infusion required in 100 mL of sodium chloride 9 mg/mL (0,9 %) solution for infusion. It is recommended to deliver the total volume of the infusion using a 0,2 µm in line filter. Care must be taken to ensure the sterility of the prepared solution since ELAPRASE does not contain any preservative or bacteriostatic agent; aseptic technique must be observed. Once diluted, the solution should be mixed gently, but not shaken.
3. The solution should be inspected visually for any discolouration prior to administration. Do not shake.
4. It is recommended that administration is started as soon as possible.
5. Do not infuse ELAPRASE concomitantly in the same intravenous line with other medicines.
6. For single use only. Discard of any unused product appropriately.