

ELAPRASE®

Idursulfase 6 mg/3 mL, Concentrate for Solution for Infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Elaprase.

It does not contain all the available information about Elaprase.

It does not take the place of talking to your doctor or a trained health care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child having Elaprase against the benefits they expect it will have.

If you have any concerns about this medicine, ask your doctor or nurse.

Keep this leaflet.

You may need to read it again.

What Elaprase is used for

Elaprase is used as enzyme replacement therapy to treat Hunter syndrome (Mucopolysaccharidosis II), a rare genetic disease in which an enzyme called iduronate-2-sulfatase is missing or the level of the enzyme is lower than normal.

Hunter syndrome generally occurs in males and rarely in females.

Elaprase is available only with a doctor's prescription. Only your or your child's treating doctor can start the treatment and supervise the ongoing treatment.

Elaprase is to be given only to the person for whom it has been prescribed.

How it works

Patients with Hunter syndrome do not produce enough of their own enzyme, iduronate-2-sulfatase. The reduced iduronate-2-sulfatase levels in patients result in the accumulation of substances called glycosaminoglycans (GAG) in a number of cells and tissues. This causes the affected cells and tissues to function abnormally, thereby causing problems for various organs in the body.

Elaprase is an enzyme replacement therapy that is intended to restore sufficient levels of enzyme to assist in the removal of the accumulated substances and to reduce further accumulation.

Ask your treating doctor if you have any questions about why it has been prescribed for you or your child.

Before you are given Elaprase

When you or your child must not be given it

Do not take Elaprase if you or your child have a known, severe, life-threatening allergic reaction to:

- idursulfase
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- shortness of breath
- faintness or dizziness
- headaches

- skin rash, itching or hives
- swelling

If you are not sure whether you or your child should have Elaprase, talk to your doctor or nurse.

Before you or your child are given it

Tell your doctor if you or your child have had reactions to any previous treatments, including any of the following reactions:

- allergic reaction
- difficulty breathing

Tell your doctor if you or your child have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you or your child is suffering from any of the following:

- Respiratory condition
- Airway disease
- Flu-like symptoms and fever
- Heart condition

Tell your doctor if you are pregnant or intend to become pregnant.

There is no information available regarding the use of Elaprase in pregnant women.

Your doctor will discuss the possible risks and benefits of having Elaprase during pregnancy.

Tell your doctor if you are breast-feeding.

It is not known whether Elaprase passes into breast milk. If there is a need to consider using Elaprase while you are breastfeeding, your

doctor will discuss with you the benefits and risks of using it.

Tell your doctor if your child is under 16 months of age and has been prescribed Elaprase.

Safety in children below the age of 16 months has not been studied. If your child has been prescribed Elaprase, you may wish to discuss this with your child's doctor.

Taking other medicines

Tell your doctor or nurse if you or your child are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

It is not known whether there are interactions between Elaprase and other medicines.

Your doctor or nurse will advise you and decide whether or not to give you or your child Elaprase.

How Elaprase is given

How much to use

The recommended dosage for Elaprase is 0.5 mg (half a milligram) for every kg you weigh, once every week.

Your doctor will decide on the dose that is most suitable.

How to use it

Elaprase will be prepared and given to you or your child by a trained health care professional who is knowledgeable in the treatment of Hunter syndrome or other inherited metabolic disorders.

Treatment with Elaprase may be given in the clinic or in certain cases, at home.

Treatment at home must be administered by a healthcare professional. Your doctor will determine if home treatment is appropriate for you or your child.

Elaprase will be diluted in 0.9% (9 mg/mL) Sodium Chloride for Injection before use. After dilution Elaprase is given directly into the vein (intravenously). The infusion will normally last for 1 to 3 hours and will be given every week.

Infusion with Elaprase should start as soon as possible after the medicine has been diluted. If not used immediately, the solution must be stored at 2°C - 8°C and infused within 24 hours. It should be protected from light before it is given to you or your child.

If you are given too much (overdose)

There is limited information regarding overdose with Elaprase. Evidence suggests that patients may experience severe allergic reactions due to overdose.

Your doctor is trained to work out the correct dose and to contact the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) in case of an overdose.

After having Elaprase

Things you or your child must do

Keep appointments with your doctor or clinic.

It is important to have the infusion with Elaprase at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

Have any tests when your doctor says to.

Your doctor may wish to test your or your child's body's response to Elaprase to make sure that it is working.

Your doctor may wish to test for allergic reactions some time after the

infusion or continue to monitor after infusion.

Things to be careful of

Allergic reactions may occur approximately 24 hours after infusion.

Tell your health care professional immediately if you experience any allergic reactions.

Be careful driving or operating machinery until you know how Elaprase affects you.

The effect of Elaprase on your ability to drive a car or operate machinery has not been studied.

Make sure that you know how you react to Elaprase before you drive a car or operate machinery or do anything else that may be dangerous if you are dizzy, light-headed, tired or drowsy.

Side effects

Tell your doctor or nurse as soon as possible if you or your child do not feel well after having Elaprase.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects. Side effects can happen even if you or your child have been receiving treatment with Elaprase for some time.

Ask your doctor or nurse to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- Faintness or dizziness
- Headaches
- Stomach ache
- Redness of skin, itching
- Anxiety
- Vomiting

If you notice any of the following side effects tell your treating doctor immediately or go to Emergency at your nearest hospital:

- Shortness of breath
- Wheezing
- Difficulty breathing
- Inflammation of the back of the throat
- Joint pain or swelling itching with or without a rash
- Local reaction around the injection site such as swelling
- Hives
- An uncomfortable feeling in the stomach or indigestion
- Chest pain
- Fever or high temperature
- Seizure
- Loss of consciousness
- Low blood pressure

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything making you feel unwell when you are taking, or soon after you have finished taking Elaprase.

Storing Elaprase

Store Elaprase in a refrigerator at 2°C - 8°C. Do not freeze or shake.

Diluted Elaprase should be protected from light.

If not used immediately, the solution must be stored at 2°C - 8°C and infused within 24 hours.

Product Description

What it looks like

Elaprase is a clear to slightly opalescent, colourless solution.

Ingredients

Active ingredient:

idursulfase

Other ingredients:

sodium chloride, sodium phosphate - monobasic monohydrate, dibasic sodium phosphate heptahydrate, polysorbate 20.

Supplied by

In Australia this product is registered by:

sanofi-aventis australia Pty Ltd.

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