

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, 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.

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), predominantly dermatan sulphate and heparan sulphate, in a number of cell types and tissues. Elaprase is an enzyme replacement therapy

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

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:

- Elaprase
- 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 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 5 years of age and has been prescribed Elaprase Safety in children below the age of 5 years 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.

Some other medicines and Elaprase could interfere with each other. No studies have been carried out on drug interactions with Elaprase

Tell your doctor or nurse if you or your child are using other medicines as these medicines may be affected by Elaprase or may affect how well it works

(different amounts of these medicines may be needed or different medicines may need to be taken). Your doctor or nurse will advise you and decide whether or not to give you or your child Elaprase.

How Elaprase is given

Elaprase will be given to you or your child directly into the vein (intravenously) by a trained health care professional in a hospital or a clinic. It is recommended that this infusion be given once every week and each one will be given over 1 to 3 hours.

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

If you are given too much (overdose)

There have been no reported overdoses of 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.

After having Elaprase

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.

Things to be careful of

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.

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Side effects

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

Elaprase may have unwanted side effects in a few people. All medicines can have side effects, and sometimes they can be serious. You or your child may need urgent medical treatment if you notice some side effects.

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

You should talk to your doctor or pharmacist if you notice any of the following:

- Shortness of breath
- Faintness or dizziness
- Headaches
- Inflammation of the back of the throat
- Stomach ache
- 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
- Anxiety
- Chest pain

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

Elaprase will be stored in a refrigerator in the hospital or clinic pharmacy.

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, sodium phosphate dibasic heptahydrate, polysorbate 20

Supplied by

In Australia this product is registered by:

Genzyme Australasia Pty Ltd

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In New Zealand this product is registered by:

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