

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Elaprase?

Elaprase contains the active ingredient idursulfase. 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.

For more information, see Section [1. Why am I using Elaprase?](#) in the full CMI.

2. What should I know before I use Elaprase?

Do not use if you or your child have ever had an allergic reaction to idursulfase or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Elaprase?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Elaprase and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Elaprase?

- You will be given Elaprase by a trained healthcare professional who is knowledgeable in the treatment of Hunter syndrome or other inherited metabolic disorders.
- Elaprase is given directly into the vein (intravenously). The infusion will normally last for 1 to 3 hours and will be given every week

More instructions can be found in Section [4. How do I use Elaprase?](#) in the full CMI.

5. What should I know while using Elaprase?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you or your child are using Elaprase.• Keep your appointments.• Have any tests when your doctor says to |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools 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 |
| Looking after your medicine | <ul style="list-style-type: none">• Elaprase should be stored in a refrigerator at 2°C - 8°C. Do not freeze or shake.• Once 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. |

For more information, see Section [5. What should I know while using Elaprase?](#) in the full CMI.

6. Are there any side effects?

Common side effects: Faintness, dizziness, headaches, stomach aches, itching, skin redness, anxiety and vomiting.

Serious side effects: Inflammation of the back of the throat, localised swelling near injection site, shortness of breath, difficulty breathing, wheezing.

For more information, including what to do if you or your child have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ELAPRASE®

Active ingredient: *Idursulfase*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Elaprased. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Elaprased.

Where to find information in this leaflet:

1. [Why am I using Elaprased?](#)
2. [What should I know before I use Elaprased?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Elaprased?](#)
5. [What should I know while using Elaprased?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Elaprased?

Elaprased contains the active ingredient idursulfase.

Elaprased is an enzyme replacement therapy that is intended to restore sufficient levels of enzyme within the body.

Elaprased is used to treat Hunter syndrome (Mucopolysaccharidosis II or MPS 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 females.

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 several cells and tissues. This causes the affected cells and tissues to function abnormally, thereby causing problems for various organs in the body. Elaprased assists in the removal of the accumulated substances and to reduce further accumulation.

Elaprased 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.

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

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

2. What should I know before I use Elaprased?

Warnings

Do not use Elaprased if:

- you or your child are allergic to idursulfase, or any of the ingredients listed at the end of this leaflet.

- always check the ingredients to make sure you or your child can use this medicine.

Check with your doctor if you or your child:

- have any other medical conditions such as a respiratory condition, airway disease, flu-like symptoms, fever or a heart condition
- take any medicines for any other condition

During treatment, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether Elaprased passes into breast milk. If there is a need to consider using Elaprased while you are breastfeeding, your doctor will discuss with you the benefits and risks of using it.

Children under 16 months of age

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

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

3. What if I am taking other medicines?

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect Elaprased.

4. How do I use Elaprase?

How much to use

- The dose you receive is based on body weight.
- The recommended dosage for Elaprase is 0.5 mg/kg of body weight.

When to use Elaprase

- Elaprase is given once a week.

How to use Elaprase

- 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 or your child forget to use Elaprase

Elaprase should be used regularly at the same time each week. It is important that you go to all your appointments to make sure your treatment works. If you miss any appointments, call your doctor as soon as possible to reschedule your appointment. Your doctor will decide how the treatment will continue.

If you or your child are given too much Elaprase

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

If you think that you or your child have been given too much Elaprase, you may need urgent medical attention.

Your treating healthcare professional is trained to calculate the correct dose and to contact **the Poisons Information Centre** (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), in case of an overdose.

5. What should I know while using Elaprase?

Things you or your child should 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.

Remind any doctor, dentist or pharmacist you visit that you or your child are using Elaprase.

Call your doctor straight away if you:

Show any signs or an allergic reaction.

Allergic reactions may occur approximately 24 hours after infusion. Tell your health care professional immediately if you experience any allergic reactions.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

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

Keep it where young children cannot reach it.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• Faintness• Dizziness• Headaches• Stomach aches• Itching• Skin redness• Anxiety• Vomiting | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Allergy related side effects:</p> <ul style="list-style-type: none">• Inflammation of the back of the throat• Local reaction around the injection site such as swelling• Skin rash, itching or hives <p>Respiratory related side effects:</p> <ul style="list-style-type: none">• Shortness of breath• Wheezing• Difficulty breathing <p>Other side effects:</p> <ul style="list-style-type: none">• Joint pain or swelling, itching with or without a rash• An uncomfortable feeling in the stomach or indigestion• Chest pain• Fever or high temperature• Seizure• Loss of consciousness• Low blood pressure | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Elaprase contains

| | |
|---|--|
| Active ingredient (main ingredient) | Idursulfase |
| Other ingredients (inactive ingredients) | Sodium chloride Sodium phosphate monobasic monohydrate Dibasic sodium phosphate heptahydrate Polysorbate 20 |

Do not take this medicine if you or your child are allergic to any of these ingredients.

What Elaprase looks like

Elaprase is a clear to slightly opalescent, colourless solution.

The strength is 6mg/3mL.

Each pack contains 1 vial.

AUST R 129481

Who distributes Elaprase

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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