

ELAPRASE®

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 to treat Hunter syndrome, a rare genetic disease in which an enzyme called iduronate-2-sulfatase is missing or the level of 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 Elaprase 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.
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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 Elaprase. **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 Elaprase.**

Where to find information in this leaflet:

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

1. Why am I using Elaprase?

Elaprase contains the active ingredient idursulfase. Elaprase is an enzyme replacement therapy that is intended to restore sufficient levels of enzyme within the body.

Elaprase 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.

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.

2. What should I know before I use Elaprase?

Warnings

Do not use Elaprase 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 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 Elaprase in pregnant women.

Talk to your doctor if you are breastfeeding or intend to breastfeed. 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 risk of using it.

Children under 16 months of age

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 Elaprase, 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 Elaprase 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 Elaprase.

4. How will Elaprase be given?

How much to use

- The dose you receive is based on your body weight
- The recommended dose is 0.5 mg/kg of body weight

When to use Elaprase

- Elaprase will be given to you once a week

How to inject 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.

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

Your healthcare professional is trained to calculate the correct dose and to contact the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand).

5. What should I know while using Elaprase?

Things you or your child should do:

Keep your appointments.

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 you or your child's body's response to Elaprase to make sure that it is working. Your doctor may also wish to test for allergic reactions some time after the infusion or to continue to monitor after infusion.

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

Things to be careful of:

Allergic reactions

Allergic reactions may occur approximately 24 hours after infusion.

Tell your healthcare 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.

Looking after your medicine

- 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.

Keep it where young children cannot reach it.

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 	<p>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 651 533">Allergy related side effects:</p> <ul data-bbox="204 568 778 981" style="list-style-type: none"><li data-bbox="204 568 778 674">● Inflammation of the back of the throat<li data-bbox="204 696 778 860">● Local reaction around the injection site such as swelling<li data-bbox="204 882 778 981">● Skin rash, itching or hives <p data-bbox="204 1010 756 1111">Respiratory related side effects:</p> <ul data-bbox="204 1146 671 1335" style="list-style-type: none"><li data-bbox="204 1146 671 1196">● Shortness of breath<li data-bbox="204 1218 671 1267">● Wheezing<li data-bbox="204 1290 671 1335">● Difficulty breathing <p data-bbox="204 1357 628 1406">Other side effects:</p> <ul data-bbox="204 1442 778 1982" style="list-style-type: none"><li data-bbox="204 1442 778 1606">● Joint pain or swelling, itching with or without a rash<li data-bbox="204 1628 778 1783">● An uncomfortable feeling in the stomach or indigestion<li data-bbox="204 1805 778 1854">● Chest pain<li data-bbox="204 1877 778 1982">● Fever or high temperature	<p data-bbox="817 432 1378 819">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>

Serious side effects	What to do
<ul style="list-style-type: none"> • Seizure • Loss of consciousness • Low blood pressure 	

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 to Medsafe 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

12-24 Talavera Road

Macquarie Park NSW 2113

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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