

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. WHY AM I HAVING ELFABRIO?

ELFABRIO contains the active ingredient pegunigalsidase alfa. ELFABRIO is a medicine used to treat Fabry disease, a rare genetic disorder which is caused by a deficiency in an enzyme called alpha-galactosidase A that breaks down a fatty substance in the body.

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

2. WHAT SHOULD I KNOW BEFORE I HAVE ELFABRIO?

Do not use if you have had a serious allergic or hypersensitivity reaction to pegunigalsidase alfa in the past, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you 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 have ELFABRIO?](#) in the full CMI.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor about any other medicines you are taking.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. HOW IS ELFABRIO GIVEN?

ELFABRIO will be given to you by a doctor or nurse as a slow infusion (drip) into a vein every 2 weeks. The dose your doctor chooses will depend on your body weight.

More information can be found in Section [4. How is ELFABRIO given?](#) in the full CMI.

5. WHAT SHOULD I KNOW WHILE HAVING ELFABRIO?

Things you should do	<ul style="list-style-type: none">• Tell your doctor or nurse straight away if you feel unwell, have a reaction or experience any serious side effects during or after receiving ELFABRIO (see Section 6. Are there any side effects?).• Keep all your doctor's appointments so that your progress can be checked.• Remind any doctor, dentist or pharmacist you visit that you are having ELFABRIO.
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 ELFABRIO affects you.
Looking after your medicine	<ul style="list-style-type: none">• ELFABRIO will be stored in a refrigerator between 2°C to 8°C.• Any diluted solution that is not used will be thrown away by your doctor or nurse.

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

6. ARE THERE ANY SIDE EFFECTS?

Less serious side effects may include: weakness, feeling or being sick, abdominal pain or discomfort, diarrhoea, chest discomfort or pain, headache, muscle or joint pain, sensation of numbness, tingling or pins and needles, and feeling agitated.

Serious side effects may include: hypersensitivity (allergic) reactions (such as rash, itching, hives on the skin; swollen face, tongue, throat or other parts of the body; shortness of breath, wheezing or problems breathing) and infusion-related reactions (such as pain, rash, itching, redness or swelling at the infusion site; chills, dizziness).

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



This medicine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ELFABRIO[®]

Active ingredient: *pegunigalsidase alfa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ELFABRIO. **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 ELFABRIO.**

Where to find information in this leaflet:

- [1. Why am I having ELFABRIO?](#)
- [2. What should I know before I have ELFABRIO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ELFABRIO given?](#)
- [5. What should I know while having ELFABRIO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. WHY AM I HAVING ELFABRIO?

ELFABRIO contains the active ingredient **pegunigalsidase alfa**. ELFABRIO is an enzyme replacement therapy.

ELFABRIO is a medicine used in adults to treat **Fabry disease, a rare genetic disorder**. Patients with Fabry disease do not have enough of an enzyme, called alpha-galactosidase A, that normally breaks down a fatty substance called globotriaosylceramide. If the enzyme is not present or in low levels, the fatty substance cannot be broken down and it builds up in the organs, such as the kidney and heart, causing kidney failure and heart problems.

2. WHAT SHOULD I KNOW BEFORE I HAVE ELFABRIO?

Warnings

Do not use ELFABRIO if:

- you have had a serious allergic or hypersensitivity reaction to pegunigalsidase alfa in the past
- you are allergic to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can have this medicine.

Check with your doctor if you:

- have any other medical conditions, including any kidney problems
- take any medicines for any other condition.

During treatment, you 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 plan to become pregnant. There is very little information on the use of ELFABRIO in pregnant women.

It is not known if ELFABRIO appears in breast milk. Talk to your doctor if you are breastfeeding or plan to breastfeed. Your doctor will decide if the benefits of having this medicine are greater than the risks to your child.

Children

This medicine should not be used in children and adolescents. There is not enough information to recommend the use of this medicine for children or adolescents under the age of 18 years.

ELFABRIO contains sodium

This medicine contains 48 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you 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.

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

4. HOW IS ELFABRIO GIVEN?

How much is given

- Your doctor will decide what dose you will have depending on your body weight
- The usual dose is 1 mg/kg of body weight given every 2 weeks.

How it is given

- Your doctor will work out how many vials you will be given and how much sodium chloride 0.9% solution they need to be diluted with. This will be based on your body weight.
- They will also work out how long it will take to give you the infusion. This will depend on whether it is your first or following infusion, and whether you have had any reactions to the infusion.
- The solution will be given to you as a slow infusion (drip) into a vein under the supervision of your doctor or nurse
- Your doctor or nurse will monitor you during and after the infusion in case you have a reaction to ELFABRIO (see Section [6. Are there any side effects?](#))
- If you have previously had a reaction to ELFABRIO or another enzyme replacement therapy your doctor may prescribe pre-treatment with antihistamines and/or corticosteroids before you start having ELFABRIO
- Talk to your doctor if you would like to be treated at home. Your doctor may consider home infusion if you are tolerating the infusions well.

If you have too much ELFABRIO

It is unlikely that you will receive too much ELFABRIO, however if you think you have received too much, tell your doctor or nurse straight away. Your doctor or nurse will treat and monitor your side effects.

You can also contact the Poisons Information Centre (**by calling 13 11 26**) if you have any concerns.

5. WHAT SHOULD I KNOW WHILE HAVING ELFABRIO?

Things you should do

Tell your doctor or nurse straight away if you think you are having:

- an allergic (hypersensitivity) reaction that may include swelling of the face, mouth and throat, wheezing, low blood pressure, hives, difficulty swallowing, rash, shortness of breath, flushing, chest discomfort, itchiness, sneezing and nasal congestion
- an infusion-related reaction which may include symptoms such as dizziness, headache, nausea, low blood pressure, tiredness and fever.

These reactions usually appear during or soon after the infusion. Your doctor or nurse will stop the infusion to monitor the signs and symptoms, and/or slow it down. They may also decide to completely stop your infusion depending on how serious the side effects are.

You may be treated with medicines to manage the reaction such as anti-allergy (antihistamine), anti-inflammation (corticosteroid) or anti-fever (antipyretic) medicines. Your doctor might do a blood test to check for antibodies that might affect your treatment.

Other things you should do:

- keep all of your doctor's appointments so that your progress can be checked
- remind any doctor, dentist or pharmacist you visit that you are having ELFABRIO.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ELFABRIO affects you.

ELFABRIO may cause vertigo (a spinning sensation) or dizziness in some people. If you feel dizzy or vertigo on the day of treatment, do not to drive or use machines until you feel better.

Looking after your medicine

- ELFABRIO will be stored for you by your doctor, pharmacist or nurse. Store at 2°C to 8°C (Refrigerate. Do not freeze).
- After dilution, the diluted solution should be used immediately. If not used immediately, the diluted solution should be stored for no longer than 24 hours in a refrigerator (2°C to 8°C) or for no longer than 6 hours at room temperature (below 25 °C).
- Do not shake or agitate the vials
- Do not use if you notice particles or discolouration.

Keep it where young children cannot reach it.

When your medicine will be discarded

- Any diluted solution that is not used after 24 hours (if stored in the refrigerator) or 6 hours (if stored at room temperature) will be thrown away by your doctor or nurse
- It will also be thrown away if the expiry date has passed.

6. ARE THERE ANY SIDE EFFECTS?

All medicines can have side effects. If you 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, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Circulation:</p> <ul style="list-style-type: none"> flushing low or high blood pressure swollen lymph nodes <p>Digestive system:</p> <ul style="list-style-type: none"> feeling or being sick abdominal pain or discomfort diarrhoea reflux or indigestion stomach irritation and pain wind <p>Ear, nose, throat and mouth:</p> <ul style="list-style-type: none"> irritated throat stuffy nose sneezing <p>General body:</p> <ul style="list-style-type: none"> feeling dizzy or giddy feeling numb, weak or exhausted having chills chest discomfort and chest pain pain in the arms and legs flu-like symptoms nipple pain fever or increased body temperature weight gain <p>Heart:</p> <ul style="list-style-type: none"> palpitations (extra heart beats) slow heart rate weakening of the left side of the heart <p>Kidneys:</p> <ul style="list-style-type: none"> pink, brown, foamy or bubbly urine kidney disease with swollen legs, ankles or feet, drowsiness, shortness of breath or fatigue <p>Lungs:</p> <ul style="list-style-type: none"> sudden wheezing and coughing problems breathing <p>Mental health:</p> <ul style="list-style-type: none"> feeling nervous or agitated problems sleeping <p>Muscles and bones:</p> <ul style="list-style-type: none"> joint pain muscle pain or stiffness <p>Nervous system:</p> <ul style="list-style-type: none"> sensation of pins and needles headache restless legs syndrome (an urge to move the legs) tingling, numbness or burning pain nerve pain burning feeling trembling 	<p>Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.</p>

<p>Skin:</p> <ul style="list-style-type: none"> itchy or lumpy rash redness itching decreased sweating <p>Tests and investigations:</p> <ul style="list-style-type: none"> increased liver enzymes protein in the urine higher levels of urine protein in relation to creatinine white blood cells in the urine increased uric acid in the blood. 	
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Serious side effects

Serious side effects	What to do
<p>Hypersensitivity (allergic) reaction* may include:</p> <ul style="list-style-type: none"> rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body, or trouble breathing <p>Infusion-related reaction* may include:</p> <ul style="list-style-type: none"> pain, rash, itching, redness or swelling at the infusion site feeling cold (chills) dizziness. <p>*See also Section 5. What should I know while having ELFABRIO?</p>	<p>Tell your doctor or nurse straight away if you are in hospital or if you are at home, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor, nurse or pharmacist if you notice anything else that may be making you 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 experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. PRODUCT DETAILS

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

What ELFABRIO contains

Active ingredient (main ingredient)	pegunigalsidase alfa
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> sodium citrate dihydrate citric acid sodium chloride Water for injections

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

What ELFABRIO looks like

ELFABRIO is a clear, colourless solution. It is a concentrated solution that must be diluted in an infusion bag with 0.9% sodium chloride solution before it is used.

Each vial contains 20 mg of pegunigalsidase alfa in a volume of 10 mL (2 mg/mL).

ELFABRIO comes in packs containing 1, 5 or 10 vials per carton.

Not all pack sizes may be marketed.

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Who supplies ELFABRIO

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