REPLAGAL®

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 REPLAGAL?

REPLAGAL contains the active ingredient agalsidase alfa ghu. REPLAGAL is used to treat Fabry Disease.

For more information, see Section 1. Why am I using REPLAGAL? in the full CMI.

2. What should I know before I use REPLAGAL?

Do not use if you have ever had an allergic reaction to REPLAGAL 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 use REPLAGAL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REPLAGAL 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 REPLAGAL?

- Before REPLAGAL is given to you, it is mixed with 0.9% sodium chloride intravenous solution (saline). The prepared solution will be infused into a vein in your arm over a 40 minute period.
- The usual dose is an infusion of 0.2 mg for every kg you weigh.

More instructions can be found in Section 4. How do I use REPLAGAL? in the full CMI.

5. What should I know while using REPLAGAL?

Things you should do	• Remind any doctor or pharmacist you visit that you are using REPLAGAL.
Things you should not do	• Do not use any other medications while using REPLAGAL unless you have discussed this with your doctor or pharmacist.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how REPLAGAL affects you.
Looking after your medicine	• Store at 2-8°C (in a refrigerator). Do not freeze.

For more information, see Section 5. What should I know while using REPLAGAL? in the full CMI.

6. Are there any side effects?

The most commonly reported side effects are allergic reaction, headache, nausea, fatigue, diarrhoea, cough, vomiting, dizziness, pain or swelling of joints, back or limb pain, fever, flu-like symptoms, tingling or numbness in fingers or toes, abdominal pain or discomfort, shortness of breath, chest pain, palpitations, muscle pain, unusual weakness, feeling cold, rash, swelling of the hands or feet, ears ringing, and tremor or shakes.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

REPLAGAL

Active ingredient(s): *agalsidase alfa ghu*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using REPLAGAL?

REPLAGAL contains the active ingredient agalsidase alfa ghu. Agalsidase alfa ghu is a form of the human enzyme α-galactosidase A. It is produced by switching on the gene for α-galactosidase A in cells. The enzyme is then removed from the cells and made into a sterile concentrate for solution for infusion.

REPLAGAL is used to treat Fabry Disease. REPLAGAL is given as enzyme replacement therapy when the level of enzyme in the body is lower than normal as in Fabry Disease.

2. What should I know before I use REPLAGAL?

Warnings

Do not use REPLAGAL if:

- you are allergic to agalsidase alfa ghu, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- think you are allergic to any of the ingredients contained in REPLAGAL
- have previously used REPLAGAL and have had any unusual reactions such as skin rash or "flu-like symptoms" to any injections of REPLAGAL in the past
- 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 intend to become pregnant.

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

Your doctor will discuss the risks and benefits of using REPLAGAL if you are pregnant or breastfeeding.

Use in Children

REPLAGAL has not been studied in children less than 6 years old, and only limited information is available in children 7-18 years of age.

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.

Some medicines may interfere with REPLAGAL and affect how it works. These include:

- chloroquine, a medicine used to prevent or treat malaria
- amiodarone, a medicine used to treat life-threatening heart rhythm problems
- benoquin, a medicine used lighten the skin in people with a skin condition called vitiligo
- gentamicin, a medicine used to treat serious bacterial infections.

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

4. How do I use REPLAGAL?

How much is given

- The usual dose is an infusion of 0.2 mg for every kg you weigh. This would be about 14 mg or 4 vials (glass bottles) of REPLAGAL for an average size (70 kg) individual.

When you will be given REPLAGAL

- The infusion will be given every two weeks.

How REPLAGAL is given

- REPLAGAL has to be diluted in 0.9% sodium chloride intravenous solution (saline) before use. After dilution REPLAGAL is given in a vein. This will usually be in your arm.
- Each time you are treated it will take 40 minutes for REPLAGAL to be given to you in your vein. Your treatment will be supervised by a doctor who specialises in the treatment of Fabry Disease. You may need to be treated with REPLAGAL long term.
- If your conditions have been stabilised in a controlled hospital setting and you are tolerating your infusion

well, a doctor or nurse may administer REPLAGAL infusion to you at your home.

If you forget to use REPLAGAL

If you miss an infusion, the enzyme levels which REPLAGAL is intended to replace will remain low. Consult your doctor and he/she will decide when you need your next infusion.

If you stop using REPLAGAL, the level of the enzyme which is responsible for Fabry Disease will remain low and the symptoms of the disease will not be treated.

If you use too much REPLAGAL

As REPLAGAL is usually given to you by infusion under the supervision of a doctor or nurse, it is unlikely that you will receive too much. In the unlikely event that this may occur, your doctor will arrange the appropriate care.

If you think that you have used too much REPLAGAL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using REPLAGAL?

Things you should do

Make sure that all of your doctors and pharmacists know you are using REPLAGAL. Remind them if any new medicines are about to be started. Things you should not do

- Do not use any other medications while using REPLAGAL unless you have discussed this with your doctor or pharmacist.
- Do not use REPLAGAL to treat any complaint other than that directed by your doctor.
- Do not give REPLAGAL to someone else even if his/her symptoms are the same.

Infusion-related reactions

13.7% of patients treated with REPLAGAL in clinical studies have experienced reactions during or following infusion of REPLAGAL. Most reactions were mild. The most common symptoms were chills, headache, nausea, fever, facial flushing (redness) and tiredness. These reactions have generally occurred 2-4 months after the start of treatment and then decreased over time. However, they may begin more than 1 year after the start of treatment. More serious reactions with fever, chills, fast heart rate, hives, vomiting, swelling of the throat and tongue causing difficulty swallowing and breathing, have been reported uncommonly.

Most of the time you can still be given REPLAGAL even if these symptoms occur. If you experience an allergic side effect following the administration of REPLAGAL, you should immediately contact your doctor.

If symptoms occur during your infusion:

- Your doctor or nurse may stop the infusion temporarily (5-10 min) until the symptoms go away and then begin the infusion again
- Your doctor or nurse may also treat the symptoms with other medicines (antihistamines or corticosteroids)

Driving or using machines

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

REPLAGAL is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

- Store at 2-8°C (in a refrigerator). Do not freeze.

REPLAGAL will usually be kept in the pharmacy department of the hospital where you are receiving the treatment and the infusion prepared there for you individually. Any unused solution from the preparation would be discarded.

The infusion should be given immediately after preparation, unless otherwise instructed by your physician. REPLAGAL does not contain any preservatives to prevent bacterial growth.

REPLAGAL will not be given to you if there is discolouration or other foreign particles present. A slight haziness is normal.

Keep it where young children cannot reach it.

Do not use this medicine after the expiry date.

Do not use this medicine if the package is torn or shows signs of tampering.

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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache or dizziness • fever • flushing • nausea • tingling or numbness or pain in fingers or toes • change in the taste of food • increased tear secretion • ears ringing	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• tremors or shakes • prolonged sleep or difficulty staying awake • palpitations • increased blood pressure or low blood pressure • chest tightness/pain • cough • hoarseness, sore or tight throat • runny nose • vomiting • abdominal pain/discomfort • diarrhoea • acne • red or itchy or mottled skin • rash at the infusion site • back or limb pain • swelling of the extremities or joints • muscle pain • unusual weakness • fatigue • feeling cold or hot • general pain/discomfort • flu-like symptoms • generally feeling unwell	

Serious side effects

Serious side effects	What to do
• signs of infection • shortness of breath • changes in the way your heart beats (for example, if you notice it beating faster) • pain or tenderness in chest, muscles or joints • light-headedness • itching or rash • sweating	**Tell your doctor as soon as possible if you notice any of these side effects.**
• allergic reactions – symptoms include swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing and hives • high fever	**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.**

Tell your doctor 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.

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 REPLAGAL contains

Active ingredient (main ingredient)	agalsidase alfa ghu
Other ingredients (inactive ingredients)	• sodium phosphate - monobasic monohydrate • sodium hydroxide • polysorbate 20 • sodium chloride

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

What REPLAGAL looks like

REPLAGAL is a sterile, clear and colourless solution intended for intravenous administration. A minute amount of fine particulate matter, causing the solution to appear slightly hazy, may be present. (AUST R 82818).

REPLAGAL is supplied as a single vial in a carton.

Who distributes REPLAGAL

Australia:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Telephone: 1800 012 612

www.takeda.com/en-au

New Zealand:

Takeda New Zealand Limited

Level 10, 21 Queen Street

Auckland 1010

New Zealand

Telephone: 0508 169 077

www.takeda.com/en-au

This leaflet was prepared in November 2025.