REPLAGAL®

agalsidase alfa ghu 3.5 mg / 3.5 mL concentrated injection vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REPLAGAL. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start using REPLAGAL.

All medicines have risks and benefits. Your doctor has weighed the possible risks of using REPLAGAL against the expected benefits.

If you have any concerns about using REPLAGAL, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What is REPLAGAL used for

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.

Agalsidase alfa 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.

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.

Your doctor may have prescribed REPLAGAL for another use. Ask your doctor if you have any questions about why REPLAGAL has been prescribed for you.

REPLAGAL is not addictive.

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

REPLAGAL is only available on a doctor's prescription.

Before you use REPLAGAL

When you must not use it

Do not use REPLAGAL if:

- You are allergic (hypersensitive) to agalsidase alfa or any of the other ingredients of REPLAGAL
- The package is torn or shows signs of tampering

- The expiry date (EXP) printed on the pack has passed. If you use this medication after the expiry date has passed, it may not work as well

Before you start to use it

Tell your doctor if:

1. **You think you are allergic to any of the ingredients contained in REPLAGAL.**

2. **You 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**

3. **You are pregnant or intend to become pregnant, or are breastfeeding or wish to breastfeed**

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

4. **You are taking other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop**

If you have not told your doctor about any of the above, tell him/her before you use REPLAGAL.

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.

How is REPLAGAL 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.

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. The infusion will be given every two weeks.

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 it

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 (overdose)

There is no experience with overdose of REPLAGAL. In the unlikely event that this may occur, your doctor will arrange the appropriate care.

Telephone your doctor or the Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764766) for advice if you think that you or anyone else may have used too much REPLAGAL. Do this even if there are no signs of discomfort or poisoning.

While you are using REPLAGAL

Things you must 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 that you must not do

Do not use any other medications while using REPLAGAL unless you have discussed this with your doctor or pharmacist. This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Do not use REPLAGAL to treat any complaint other than that directed by your doctor. It may not be safe to use REPLAGAL for another complaint.

REPLAGAL should only be used by the person for whom it was prescribed. Do not give REPLAGAL to someone else

even if his/her symptoms are the same. It may not be safe for another person to use REPLAGAL.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using REPLAGAL.

Like all medicines, REPLAGAL can have side effects. The most commonly reported side effects reported in clinical trials of REPLAGAL were allergic reaction, dizziness, fever, flushing and nausea occurring in approximately 10% of patients. Most side effects are mild to moderate and many were associated with infusion reactions which are explained in the following paragraph. However some may be serious and may require treatment.

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)

Tell your doctor immediately if you notice any of the following:

- swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing

- high fever

- hives

Tell your doctor as soon as possible if you notice any of the following:

- 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

Other very common or common side effects include the following:

- tingling or numbness or pain in fingers or toes, change in the taste of food, increased tear secretion, ears ringing, shakes, prolonged sleep
- palpitations, increased blood pressure, low blood pressure
- cough, chest tightness/pain
- 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
- feeling cold or hot, general pain/discomfort, flu-like symptoms, generally feeling unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

After using REPLAGAL

Storage

Keep REPLAGAL out of the reach and sight of children.

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.

Do not use after the expiry date stated on the label and carton. REPLAGAL will not be given to you if there is discolouration or other foreign particles present. A slight haziness is normal.

Product description

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.

REPLAGAL is supplied as a single vial in a carton.

Ingredients

REPLAGAL contains 3.5 mg agalsidase alfa ghu, in 3.5 mL.

The other ingredients are:

- sodium phosphate - monobasic monohydrate
- sodium hydroxide
- polysorbate 20
- sodium chloride

Sponsor

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