

VPRIV®

Velaglucerase alfa ghu

Consumer Medicine Information

What is in this leaflet

Please read this leaflet before you start using VPRIV.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using VPRIV against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What VPRIV is used for

VPRIV is a long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.

Gaucher disease is a genetic disorder caused by a missing or defective enzyme named glucocerebrosidase. When this enzyme is missing or does not work properly, a substance called glucocerebroside builds up inside cells in the body. The build-up of this material causes the signs and symptoms found in Gaucher disease.

VPRIV contains a substance called velaglucerase alfa ghu which is used to replace the missing or defective enzyme, glucocerebrosidase, in patients with Gaucher disease.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

VPRIV should not be used in children under the age of 2 years.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive or use machines.

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

Before you use VPRIV

When you must not use it

Do not use VPRIV if you have an allergy (hypersensitivity) to velaglucerase alfa ghu, or any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should use VPRIV, talk to your doctor.

Before you start to use it

Tell your doctor before using VPRIV if:

- you think you are allergic to any of the ingredients contained in VPRIV
- you have previously used VPRIV and have had any unusual reactions such as skin rash or "flu-like symptoms" to any injections of VPRIV in the past
- you have had an allergic reaction to other enzyme replacement therapy you may have used for Gaucher disease

If you are treated with VPRIV, you may experience side effects during or following the infusion. These are called infusion-related reactions (see Side effects section).

Infusion-related reactions might appear as a hypersensitivity reaction with symptoms like nausea, rash, difficulty in breathing, back pain, chest discomfort (chest tightness), hives, joint pain or headache. Apart from symptoms of hypersensitivity reactions, infusion-related reactions might show as dizziness, high blood pressure, tiredness, fever, or itching.

If you experience any of the symptoms, you must tell your doctor immediately.

You may be given additional medicines to treat or help prevent future reactions.

If the reaction is severe, your doctor will stop the infusion immediately and start giving you appropriate medical treatment.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan on becoming pregnant.**Tell your doctor if you are breastfeeding or wish to breastfeed.**

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any 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 are given VPRIV.

How to use VPRIV

VPRIV is given by a doctor or nurse knowledgeable in the treatment of Gaucher disease. After dilution, VPRIV is given in a vein. This will usually be in your arm.

How much and when it is given

Dose:

The recommended dose is 60 Units of VPRIV for every kilogram you weigh.

VPRIV is given every other week.

If you are currently being treated for Gaucher disease with another ERT and your doctor wants to change you to VPRIV, you can initially receive VPRIV at the same dose and frequency you had been receiving the other ERT.

Administration:

After VPRIV has been mixed with sterile water and normal saline, it is given as an infusion into your vein over a period of 60 minutes.

Response to treatment:

Your doctor will monitor your response to treatment and may change your dose (up or down) over time.

Your doctor will tell you for how long you will need to be treated with VPRIV.

If you are tolerating your infusions well in the clinic, your doctor or nurse may administer your infusions at home under the direction of your specialist.

If you forget to use it

If you miss an infusion, consult your doctor and he/she will decide when you need your next infusion.

What will happen if I stop using VPRIV?

Your doctor will decide if you should stop using VPRIV. If you want to know what will happen if you stop using VPRIV, ask your doctor.

If you use too much (overdose)

Telephone your doctor or Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much VPRIV. Do this even if there are no signs of discomfort or poisoning.

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

While you are using VPRIV

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using VPRIV.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not use any other medications while using VPRIV unless you have discussed this with your doctor or pharmacist.

VPRIV should only be given to the person for whom it was prescribed. Do not give VPRIV to someone else even if his/her symptoms are the same. It may not be safe for another person to use VPRIV.

Side effects

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

Like all medicines, VPRIV can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience them.

Ask your doctor or pharmacist to answer any questions you may have.

In studies with VPRIV, side effects were mainly seen while patients were being infused with the medicine or shortly after the infusion was finished. These side effects, known as infusion-related reactions, included:

- headache

- dizziness
- low blood pressure
- high blood pressure
- nausea
- tiredness
- fever (increase in body temperature)

The majority of these side effects were mild in intensity.

A few patients receiving VPRIV have experienced an allergic skin reaction such as severe rash or itching. Severe allergic reactions with symptoms of difficulty in breathing, swelling of the face, lips, and tongue or throat have occurred.

Tell your doctor immediately if you experience any of these side effects.

Other side effects that have been reported with VPRIV include:

- bone pain
- joint pain
- back pain
- abdominal pain
- abnormal blood clotting
- flushing
- rapid heart beat
- developing antibodies to VPRIV
- shortness of breath
- chest discomfort
- vomiting

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using VPRIV

Storage

Keep VPRIV out of the reach and sight of children.

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

Keep the vial in the outer carton in order to protect it from light.

VPRIV 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 should be discarded.

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

VPRIV will not be given to you if there is discolouration or other foreign particles present.

Product description

What VPRIV looks like

VPRIV is a white to off-white powder. It is dissolved in sterile water and normal saline for intravenous infusion. After reconstitution, the solution contains 100 Units of velaglucerase alfa ghu per mL.

VPRIV is supplied as a single vial in a carton.

Ingredients

Active ingredient:

VPRIV contains 400 Units of velaglucerase alfa ghu.

Other ingredients:

- sucrose
- sodium citrate dihydrate
- citric acid monohydrate
- polysorbate 20

Each vial contains 12.15 milligrams of sodium.

Sponsor

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*Shire is now part of Takeda.

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