

VPRIV®

(velaglycerase alfa glu); powder for solution for infusion

Consumer Medicine Information

What is in this leaflet

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.

Please read this leaflet before you start taking VPRIV.

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

If you have any concerns about taking VPRIV, ask your doctor or pharmacist.

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

What is VPRIV used for

VPRIV is used to treat Type 1 Gaucher disease. Gaucher disease is a genetic disorder caused by a missing or defective enzyme called glucocerebrosidase. When this enzyme is missing or does not work properly, a substance called glucocerebroside builds up inside cells in the body. VPRIV is used to replace the missing or defective enzyme, glucocerebrosidase, in patients with Gaucher disease. This type of treatment is called enzyme replacement therapy (ERT).

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

VPRIV is not addictive.

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

VPRIV is only available on a doctor's prescription.

Before you take VPRIV

When you must not use it

Do not use VPRIV if:

- You are allergic (hypersensitive) to velaglycerase alfa or any of the other ingredients of VPRIV.
- The package is torn or shows signs of tampering.
- The expiry date (EXP) printed on the pack has passed.
The expiration date refers to the last day of the month. If you use this medication after the expiry date has passed, it may not work as well.

Before you start to take it

Tell your doctor if:

1. **You think you are allergic to any of the ingredients contained in VPRIV.**
2. **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.**
3. **You have had an allergic reaction to other enzyme replacement therapy you may have used for Gaucher disease.**
4. **You are pregnant or intend to become pregnant or are breastfeeding or wish to breastfeed.**
Your doctor will discuss the risks and benefits of taking VPRIV if you are pregnant or breastfeeding.

5. 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 are given VPRIV.

VPRIV should not be used in children under the age of 2 years. VPRIV may be given to children and adolescents (2 to 17 years of age) at the same dose and frequency as in adults.

How is VPRIV given

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 is used and when is it given

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

VPRIV is given every other week.

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

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. In clinical studies, doses ranging from 15 Units/kg to 60 Units/kg have been used.

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.

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.

What should I do if I miss an infusion?

Consult your doctor and he or she will decide when you need your next infusion.

What will happen if I stop taking VPRIV?

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

Overdose

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

For advice on the management of overdose, contact the Poisons Information Centre (phone 13 11 26).

While you are taking VPRIV

Things you must do

Make sure that all of your doctors and pharmacists know you are taking VPRIV. Remind them if any new medicines are about to be started including over the counter medicines.

Things that you must not do

Do not use any other medications while using VPRIV 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.

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 receiving VPRIV.

Like all medicines, VPRIV can have side effects. Do not be alarmed by the following list of possible side effects. You may not experience any of them.

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 reaction 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

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking VPRIV

Storage

Keep VPRIV out of the reach and sight of children.

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

Do not use after the expiry date (EXP) stated on the label and carton. The expiration date refers to the last day of the month.

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

Product description

What it 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 per mL.

VPRIV is supplied as a single vial in a carton.

Ingredients

VPRIV contains 400 Units of velaglucerase alfa ghu.

The other ingredients in VPRIV are:

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

Sponsor

Shire Australia Pty. Limited
Level 6
123 Epping Rd
North Ryde
NSW 2113 Australia

This leaflet was prepared in June 2015.

Australian Registration Number:
AUST R 180965

VPRIV is a registered trademark of Shire Human Genetic Therapies, Inc., USA.