

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 VPRIV?

VPRIV contains the active ingredient velaglucerase alfa ghu. VPRIV is a long-term enzyme replacement therapy (ERT) for patients with Gaucher disease.

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

2. What should I know before I use VPRIV?

Do not use if you have ever had an allergic reaction to VPRIV 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.

VPRIV should not be used in children under the age of 4 years.

For more information, see Section [2. What should I know before I use VPRIV?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VPRIV 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 VPRIV?

- After VPRIV has been mixed with sterile water and normal saline, it is given as an infusion into your vein in your arm over a period of 60 minutes.
- The recommended dose is 60 Units of VPRIV for every kilogram you weigh.

More instructions can be found in Section [4. How do I use VPRIV?](#) in the full CMI.

5. What should I know while using VPRIV?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using VPRIV.• If you become pregnant while using this medicine, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none">• This medicine is not expected to affect your ability to drive or use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store VPRIV at 2°C - 8°C (in a refrigerator). Do not freeze it.

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

6. Are there any side effects?

If you are treated with VPRIV you may experience infusion-related reactions such as hypersensitivity reaction with symptoms like nausea, rash, 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 or itching. A few patients receiving VPRIV have experienced severe allergic reactions with symptoms of difficulty in breathing, swelling of the face, lips, and tongue or throat.

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.

VPRIV

Active ingredient(s): Velaglucerase alfa ghu

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. [Why am I using VPRIV?](#)
2. [What should I know before I use VPRIV?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use VPRIV?](#)
5. [What should I know while using VPRIV?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using VPRIV?

VPRIV contains the active ingredient **velaglucerase alfa ghu**. Velaglucerase alfa ghu is used to replace the missing or defective enzyme, glucocerebrosidase, in patients with 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 is used as a long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.

2. What should I know before I use VPRIV?

Warnings

Do not use VPRIV if:

- you are allergic to velaglucerase 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 VPRIV.
- 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.
- have had an allergic reaction to other enzyme replacement therapy you may have used for Gaucher disease.
- have allergy to any other medicines or substances, such as foods, preservatives or dyes.
- have any other medical conditions.
- 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 possible risks and benefits of using VPRIV if you are pregnant or breastfeeding.

Use in Children

- VPRIV should not be used in children under the age of 4 years.

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 VPRIV and affect how it works.

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

4. How do I use VPRIV?

How much is given

- The recommended dose is 60 Units of VPRIV for every kilogram you weigh.
- Your doctor will monitor your response to treatment and may change your dose (up or down) over time.

When you will be given VPRIV

- VPRIV is given every other week.
- Your doctor will tell you for how long you will need to be treated with VPRIV

How VPRIV is given

- VPRIV is given by a doctor or nurse knowledgeable in the treatment of Gaucher disease.
- VPRIV is dissolved in sterile water and normal saline. After dilution VPRIV is given in a vein. This will usually be in your arm.
- VPRIV is given as an infusion into your vein over a period of 60 minutes.
- 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.

- 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 VPRIV

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

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much VPRIV

As VPRIV 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 VPRIV, 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 VPRIV?

Things you should do

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

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

If you do not feel well while you are using VPRIV.

Remind any doctor, dentist or pharmacist you visit that you are using VPRIV.

Infusion-related reactions

If you are treated with VPRIV, you may experience side effects during or following the infusion. These are called infusion-related reactions and might appear as a hypersensitivity reaction with symptoms like nausea, rash, 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.

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.

A few patients receiving VPRIV have experienced an allergic skin reaction such as severe rash and 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.

Driving or using machines

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date printed on the pack.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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
<ul style="list-style-type: none">• headache• dizziness• low blood pressure• high blood pressure• nausea• tiredness• fever• abdominal or back pain• flushing• vomiting	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shortness of breath• bone or joint pain• abnormal blood clotting• rapid heart beat or chest discomfort (chest tightness)• developing antibodies to VPRIV	Tell your doctor as soon as possible if you notice any of these side effects.
<ul style="list-style-type: none">• allergic reactions – symptoms include severe skin rash, itching or hives, swelling of the face, lips and tongue or throat and difficulty breathing	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 VPRIV contains

Active ingredient (main ingredient)	velaglucerase alfa ghu
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sucrose• sodium citrate dihydrate• citric acid monohydrate• polysorbate 20
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Do not take this medicine if you are allergic to any of these ingredients.

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. (AUST R 180965).

VPRIV is supplied as a single vial in a carton.

Who distributes VPRIV

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

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