VPRIV® Treatment by Home Infusion

Guide for Homecare Nurse / Patient / Caregiver including Infusion Diary

This guide is intended for use by Homecare Nurse / Patient Caregiver only, in conjunction with the VPRIV® SmPC. This resource was developed by Takeda as part of a commitment made in the Risk Minimisation Measures for VPRIV®. Please report any suspected adverse drug reactions via HPRA Pharmacovigilance Website: www.hpra.ie. Adverse events should also be reported to Takeda at AE.GBR-IRL@takeda.com:
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Home Infusion of VPRIV®

Some patients with Type 1 Gaucher disease treated with VPRIV® (velaglucerase alfa) may opt to receive infusions at home. The decision to receive infusions at home should be made by the patient and treating physician after three well-tolerated VPRIV® infusions under medical supervision in a hospital, clinic or office setting to ensure satisfactory tolerance of the infusions.

How to Qualify for Home infusion of VPRIV®

Patients who the treating physician may qualify for home infusion have had at least three consecutive well-tolerated VPRIV® infusions in the hospital, clinic or office setting. The physician has considered them to be medically stable and have a history of adherence to their infusion schedule. The homecare nurse, patient and caregiver must be educated about home infusion, the associated risks, the possible complications, and the provision of medical assistance at home, including emergency contact details. The home environment must be conducive to the home infusion process, safe (clean, hygienic, storage area for supplies, drug and emergency medication), and adequately equipped. The homecare nurse and patient caregivers must maintain rapid and reliable communication measures with the treating physician, or the caregiver must be adequately trained. In addition, the homecare nurse or the caregiver are adequately trained in administering VPRIV®.

How to recognise and notify the healthcare nurse and/or treating physician about adverse event reports

The most commonly observed symptoms of infusion-related reactions (IRR) (IRRs are defined as any adverse drug reaction occurring within 24 hours after the initiation of velaglucerase alfa infusion) are: headache, dizziness, hypotension (low blood pressure), hypertension (high blood pressure), nausea, fatigue/weakness and pyrexia (body temperature increased). In patients who had not used VPRIV® before, the majority of infusion-related reactions occurred during the first 6 months of treatment. Additional infusion-related reactions of chest discomfort, dyspnoea (difficulty breathing), and pruritus (skin itching) have been reported since VPRIV® was marketed.

Although rarer, hypersensitivity reactions, including symptoms consistent with anaphylaxis (severe allergic reaction), have been reported in patients using VPRIV®. The most frequently reported symptoms of hypersensitivity include nausea, rash, dyspnoea (difficulty breathing), back pain, chest discomfort or tightness, urticaria (hives), arthralgia (pain in the joints), and headache. If the patient experiences a reaction suggestive of hypersensitivity, subsequent testing for velaglucerase alfa antibodies is advised. The healthcare nurse or prescribing physician should be notified immediately.

Antibody testing

In case of suspected development of infusion-related reactions/hypersensitivity, types of allergic reactions or side effects/ adverse reactions or at the discretion of the treating physician based on his/her assessment of the response to the medication, a blood sample may be collected promptly in order to test if the patient has developed antibodies against the medication. It is very important that the homecare nurse, and/or patient caregiver report infusion-related reactions, hypersensitivity reactions, adverse reactions, or any suspicion about the infusion not working normally to the treating physician.

How to manage infusion-related reactions, hypersensitivity and/or adverse reactions is further outlined in the Emergency Plan

If an infusion-related reactions occurs during administration, including a hypersensitivity reaction, discontinue the infusion immediately. The homecare nurse, patient and caregiver must contact the treating physician as the management of these reactions would be based on severity of the reaction, such as slowing the infusion rate, treatment with medications such as antihistamines, antipyretics and/or corticosteroids, and/or stopping and resuming treatment with an increased infusion time.

Subsequent infusions may need to occur in hospital. If the patient has had a previous experience with adverse reactions during an infusion, you may be told to take an antihistamine and/or corticosteroid before the infusion to help prevent an allergic reaction from happening.

The nurse, patient and caregiver must communicate any events during and after the infusion to the treating physician, and to update the Infusion Diary

In the event of an infusion-related reaction or hypersensitivity, the homecare nurse, the patient or caregiver should discontinue the infusion immediately and telephone/contact the treating physician using the information provided in the Infusion Diary. Such events must be documented in the Infusion Diary also. When such a reaction is observed, it is important that antibody blood testing be considered and promptly obtained, as warranted.

The Infusion Diary should include the infusion plan determined by the treating physician as well as a record of the actual infusions administered including health status of the patient before, during and after infusion. The document should accompany the patient and be shared with the treating physician on each visit.

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What to expect during a home infusion of VPRIV®

If you are feeling unwell, please check with your healthcare provider to decide if your infusion should be postponed until you are feeling better. The homecare nurse may need to take a blood sample to see if you are producing antibodies against VPRIV®, especially if you have an adverse reaction during the infusion process. Your doctor will have discussed these requirements with you beforehand.

VPRIV® is dosed according to body weight. Your doctor will have provided your homecare nurse or caregiver with the necessary information for calculating the correct dose in the Infusion Diary. VPRIV® is supplied as a powder and must be reconstituted immediately before use. The homecare nurse or caregiver will mix the required amount of powder with the appropriate amount of sterile water. To make sure that no VPRIV® is wasted, you should be present when the medication is being prepared. If you are not able to start the infusion right away, reconstituted VPRIV® can be stored in a fridge at 2–8 ºC for up to 24 hours. The homecare nurse or caregiver will mix the reconstituted VPRIV® with a bag of saline solution and attach the bag to the IV administration set. The VPRIV® infusion will take about an hour, the homecare nurse will monitor you regularly and will make further notes in the infusion diary.

How to get ready for an infusion

1. Approximately 30 minutes before the infusion, remove the appropriate number of vials from the refrigerator to reach room temperature.
2. The healthcare provider will explain how many vials to use to provide the correct dose. DO NOT alter this dose.
3. Confirm that each vial is within the expiry date, which is printed on the vial and outer carton (the expiry date refers to the last day of the month indicated). DO NOT use after the expiry date.
4. Before beginning, ensure that the area used for preparing VPRIV® is thoroughly cleaned.
5. Lay out the material
6. Wash hands and keep the area clean and germ-free while preparing the solution.

Wash hands

Clean area

Wear gloves

How will the homecare nurse or caregiver insert the needle in the vein (if a central venous access device is not available)?

1. Ensure that the infusion system (infusion line connected to IV bag containing VPRIV®) is within reach and that swabs, plasters, chlorhexidine and medical tape are close by.
2. Remove the butterfly needle from the packaging.
3. The patient will sit down and rest one arm on a table (preferably on a clean cloth).
4. The homecare nurse or caregiver will apply a tourniquet above the site of the infusion.
5. Prepare the infusion site by carefully wiping the skin with a disinfection swab. Allow the skin to dry before inserting the butterfly. Always use a new sterile needle for the infusion. Never re-use needles or syringes.
6. Remove the cap from the butterfly needle and insert the needle into a vein at as shallow an angle as possible.
7. Loosen the tourniquet and make sure that the needle is in a vein by pulling back the plunger gently (you should see backflow of blood into the butterfly tube).
8. To avoid needle movement during the infusion, tape the winged adapter to the skin using medical tape.

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What will be needed to facilitate the infusion?

Medication and materials will be supplied by the hospital/pharmacy or via a third party with the appropriate prescription:

Medication

Appropriate number of vials of VPRIV® (400 U per vial) for the prescribed dose; VPRIV® vials should be stored in a refrigerator at a temperature between 2°C and 8°C.

Materials

- Sterile water for injections to reconstitute VPRIV®
- NaCl 0.9% intravenous solution, one (1) to two (2) 100ml bag(s) for IV administration
- NaCl 0.9% intravenous solution, two (2) 50ml bags or vials to flush infusion line pre- and post-infusion
- Chlorhexidine 0.5% in alcohol 70% (antiseptic solution)
- Appropriate number of 5ml and 50ml syringes depending upon dose of VPRIV®
- Sterile hypodermic needles and one (1) butterfly needle
- Tourniquet
- One (1) in-line low protein-binding 0.2 micron filter
- One (1) infusion set **or** one (1) combined infusion set with filter
- Hypodermic needle tray; Micropore tape; Mediswabs; Sharps bin; Hand wash
- Additional material may be needed if there is a central venous access device for the delivery of VPRIV®. The caregiver will be shown how to care for the device.
- If required, pre-medication (antihistamines and/or corticosteroids) to be given as per the healthcare provider's instructions. These will be prescribed and used on an individual patient basis as outlined in the Emergency Plan.

Detailed description of the administration procedures of VPRIV® and dosage and infusion rate

The homecare nurse and patient caregiver should ensure that they have received training and understand the administrative logistics of home-infusion of VPRIV®:

How the product should be reconstituted

1. Using the aseptic technique, add Sterile Water for Injection to each vial as shown in the table below:

Solution	400 Units/vial
Volume of Sterile Water for Injection	4.3ml
Concentration after reconstruction	100 Units/ml
Withdrawal volume	4.0ml

2. Upon reconstitution, mix vials by gently rolling between hands. **DO NOT SHAKE.**
3. Prior to dilution, visually inspect the solution in the vials. The solution should be clear to slightly opalescent and colourless. The solution must not be use if it is discoloured or if foreign particles are present.

PLEASE NOTE: The patient should be present prior to reconstitution, to avoid waste.

How the product should be diluted for intravenous administration

1. Withdraw the calculated volume of VPRIV® from the appropriate number of reconstituted vials. Some solution will remain in the vial (withdrawal volume = 4.0ml for 400 Unit vial).
2. Dilute the total volume of VPRIV® required in 100ml of 0.9% sodium chloride solution for infusion.
3. Mix gently. **DO NOT SHAKE.**

From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and must not exceed 24 hours at 2–8 °C. Any unused solution should be disposed of in accordance with local requirements.

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Ongoing Administration

VPRIV® is intended for IV infusion only. VPRIV® should be administered over a period of 60 minutes. VPRIV® should not be infused with other products in the same infusion tubing, as the compatibility in solution with other products has not been evaluated. The diluted solution should be filtered through an in-line low protein-binding 0.22 µm filter during administration.

1. Attach the IV tubing to the diluted bag of VPRIV® and prime the IV tubing with normal saline solution, expelling all air.
2. Set the infusion rate. VPRIV® should be administered over a period of 60 minutes.
3. Obtain IV access and attach the IV giving set. Follow local/facility protocols for IV insertion and infusion of medication.
4. Monitor the infusion regularly for infusion-related reactions.
5. When the infusion is complete, flush the tubing with normal saline to ensure residual VPRIV® remaining in the tubing is infused.
6. Remove the venous access device and discard in an infectious waste disposal container.

The homecare nurse/patient caregiver must document the following information in the infusion diary: date, dose, route of administration, injection site, time infusion started and stopped and patient response to infusion.

How to administer the medication?

If the patient has a central venous access device (in-dwelling central line), the homecare nurse or the caregiver have been shown how to care for the device.

1. Attach the infusion line to the butterfly needle or to the patients in-dwelling central line as shown by the doctor.
2. Attach the IV bag containing VPRIV® to the drip stand and open the valve. Set the infusion rate determined by the treating physician.
3. Closely observe for any occurrence of infusion-related reactions (see safety information).
4. At the end of the infusion, to ensure that the total treatment dose is administered, rinse the tubing using a 50ml bag of 0.9% NaCl, without increasing the infusion rate. In case of failure to gain venous access; or development of excessive bleeding, pain, swelling or severe bruising; or failure to infuse VPRIV® into a vein correctly, please contact the treating physician immediately.
5. Remove the butterfly needle and discard in an infectious waste disposal container. For a central venous access device, follow the technique for proper care as shown by the healthcare provider or homecare nurse.
6. Any unused solution should be disposed of in accordance with local requirements as indicated by the healthcare provider or nurse.
7. Document the following in the infusion diary: date, dose, route of administration, injection site, time infusion started and stopped and patient response to infusion.
8. If aware that a mistake was made while preparing and/or administering the drug, please contact the healthcare provider. If the error occurred during the preparation step, do not administer the drug. If the error occurred during the administration, check with the healthcare provider before giving another infusion.

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Emergency Plan for Home Infusion of VPRIV® 400 Units powder for solution

[Treating Physician to provide individual instructions for homecare nurse/patient caregiver below.]

Remind the homecare nurse, patient/caregiver of necessary actions in the event of a serious infusion reaction, hypersensitivity reaction and/or adverse reaction::

1. Stop the infusion	☐
2. Call the national emergency number	☐
3. Call the treating physician	☐
4. If the homecare nurse is present, they will obtain a blood sample for antibody testing	☐
5. If the homecare nurse is not present, they will arrange for collection of the sample	☐

Infusion Diary for VPRIV® 400 Units powder for solution for Home Infusion

The Infusion Diary should be completed and maintained by the treating physician, homecare nurse, patient/caregiver in collaboration.

Patient
Name :
Address :
City :
Telephone
Email :
Caregiver (if applicable)
Name :
Address :
City :
Telephone
Email :
Treating Physician
Name :
Address :
City :
Telephone
Email :
Nurse
Name :
Address :
City :
Telephone
Email :
Pharmacy
Name :
Address :
City :
Telephone
Email :
National Emergency Number
Telephone : 112 / 999

General Information
Administration Details

VPRIV® administered since (DD/MM/YYYY):
First VPRIV® infusion at home (DD/MM/YYYY):
VPRIV® dose, frequency:
VPRIV® infusion rate:
Indicate support to be provided by nurse:

Infusion number :
Date of infusion
Name of person giving the infusion (patient, caregiver or homecare nurse):
Patient's general health:
Patient's weight (kg):
Dose and rate of infusion:
Lot number:
Numbers of vials used:
Expiry date:
Time infusion started:
Time infusion stopped:
General remarks:
Any problems related to infusion? *
Any action taken:

*Remember that a blood sample should be obtained promptly for suspected IRR or hypersensitivity Reactions.

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