VPRIV®

[Velaglucerase alfa]

Velaglucerase alfa Treatment by Home Infusion

Guide for Homecare Nurse/Patient/ Caregiver including Infusion Diary

IMPORTANT INFORMATION on minimising the risk of infusion related reactions including hypersensitivity reactions

Please read this guide thoroughly and carefully before using this medicine

This resource has been developed by Takeda Pharmaceutical Company as part of its commitment to additional risk minimisation measures for velaglucerase alfa, in alignment with the Risk Management Plan (EU Version 13.4, November 2024).

This guide is intended for patients who have been prescribed Velaglucerase alfa 400 Units powder for solution for infusion, and their caregivers and healthcare professionals (HCPs) who may assist them with home infusion.

This document has been approved by HPRA in June 2025

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01. Objectives of this guide

The objective of this document is to provide guidance to assist homecare nurses/patients/caregivers to minimise the risks of infusion related reactions (IRRs) including hypersensitivity reactions due to home infusion.

You have received this guide because your treating physician has prescribed you velaglucerase alfa as a treatment for Gaucher Disease.

Depending on your situation, the homecare nurse may administer your medication, or you may be allowed to infuse the medicine yourself at home after you or your caregiver have been appropriately trained.

Please make sure to carefully read the Patient Information Leaflet along with this guide.

This guide will provide you correct preparation and administration technique of velaglucerase alfa. It is important to adhere to the correct dosing and infusion rate as prescribed by the physician.

- **Keep this guide throughout the duration of home infusions**. It contains your Infusion Diary, which you will need to fill in after each infusion. You must always bring your Infusion Diary to each appointment with your treatment team.
- **Talk to your doctor or healthcare professional if you experience any side effects**. This includes any possible side effects, even if not listed in this guide.
- You, your homecare nurse or your caregiver must be educated about the associated risks, the possible complications, provision of medical assistance at home, and how to act in an emergency.
- Any medication prescribed by the treating physician for pre-treatment, and/or treatment of any IRRs should be readily available and you, your homecare nurse or caregiver should know how to utilise the medications for pre-treatment and/or treatment of serious IRRs when needed.
- **See section 03** for information on signs and symptoms related to IRRs and recommended actions for the management of the side effects.
- If a serious IRRs reaction occurs, including anaphylaxis (severe allergic reaction), **immediately stop the infusion, immediately seek emergency support and contact your doctor.**

IRR/hypersensitivity symptoms include **nausea, rash, difficulty in breathing, back pain, chest discomfort (chest tightness), hives, joint pain or headache.** IRRs also include infusion-related reactions might show as **dizziness, high blood pressure, tiredness, fever, itching, blurry vision, or vomiting.**

02. Qualifying for home infusion

Some patients with Type 1 Gaucher Disease treated with velaglucerase alfa may opt to receive infusions at home. The decision to receive infusion at home should be made by the patient along with the treating physician after the patient has received three consecutive well-tolerated infusions under medical supervision in a hospital or clinic setting to ensure satisfactory tolerance of the infusions. Your physician will make the assessment to consider you as medically stable if you have demonstrated a history of adherence to your infusion schedule.

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03. Recognising infusion-related reactions including allergic reactions

Infusion-related reactions (IRRs) including allergic reactions, are a known risk which may occur within 24 hours of starting the infusion.

- These might appear as a severe allergic reaction, with **difficulty breathing, chest discomfort (chest tightness), feeling sick (nausea), swelling of the face, lips,tongue or throat (anaphylactic/anaphylactoid reactions), common is also an allergic skin reaction such as hives, severe rash or itching**.
- Apart from symptoms of hypersensitivity reactions, IRRs might show as **headache, dizziness, fever/body temperature increased, back pain, joint pain and tiredness, as well as increased blood pressure, blurry vision, and vomiting**.

Communication to the treating physician

If a serious infusion-related reaction occurs, including anaphylaxis, **immediately stop the infusion, immediately seek emergency support** and contact your doctor using the information provided in the Infusion Diary. Such events must be documented in the **Infusion Diary**.

Management of the adverse drug reactions

You may be given additional medicines to treat or help prevent future reactions. These medicines may include antihistamines, antipyretics, and corticosteroids. It is important to follow any instructions regarding medication for pre-treatment and/or treatment of serious IRRs and that patients/caregivers/nurses know how to utilise it.

04. Planning your infusion

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

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

Materials required

- Sterile water for injections to reconstitute velaglucerase alfa
- 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 velaglucerase alfa
- 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
- Infusion supplies (Hypodermic needle tray; Micropore tape; Mediswabs; Sharps bin; Hand wash; Gloves; Cotton balls/Gauze; Plaster; Drip stand). Additional material may be needed if there is a central venous access device for the delivery of the medication. 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.
- Any medication prescribed for treatment of IRRs should also be readily available

Dosing and infusion rate

- Velaglucerase alfa is dosed according to body weight.
- Your doctor should have provided you or your homecare nurse/caregiver with the necessary information for calculating the correct dose in the Infusion Diary Dose. The dose and infusion rate should not be changed without supervision of the treating physician.

Reconstitution

- **The medication is supplied as a powder and must be reconstituted immediately before use**. The required amount of powder should be mixed with the appropriate amount of sterile water.
- To make sure that no medication is wasted, the patient should be present when it is being prepared. If you are not able to start the infusion right away, reconstituted velaglucerase alfa can be stored in a refrigerator at 2–8 ºC for up to 24 hours.
- The reconstituted medication should be mixed with a bag of saline solution and the bag should be attached to the IV administration set. The infusion will take about an hour. The homecare nurse, patient/caregiver should monitor regularly and make notes in the infusion diary

Infusion Diary

It is essential to write down the details of each infusion in your Infusion Diary, including details of any reactions or side effects. You need to keep it safe and always take it to your medical appointments so you can discuss it with your doctor or treatment team.

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05. Preparing for the infusion

Inspect the velaglucerase alfa vial(s)

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

- Make sure you have the correct number of vials.
- **DO NOT** use them if the protective caps are missing or broken.
- Check that the details on the box and pharmacy labels are correct. If any details are incorrect, **DO NOT** use your medication and contact your treatment clinic immediately.
  - ✓ Check that the medication is intended for you.
  - ✓ Check that the name of your medication is correct.
  - ✓ Check that the medication has not gone past its expiry date.
- **DO NOT** use the medication if the expiry date has passed.
- Check the packaging for evidence of damage or tampering, and check the vial(s) for discoloration or visible particles ('bits' in the solution). If the liquid is not clear and colourless, or there is evidence of damage/ tampering, **DO NOT** use the medication and contact your treatment clinic immediately. **DO NOT** dispose of any unsuitable medicine, as it will need to be examined by the manufacturer to discover the reason for any fault.
- **DO NOT** try to heat the solution in the microwave, by placing the vials in hot water, or by applying heat in any other way.

Get ready for infusion

1. Approximately 30 minutes before the infusion, remove the required vials from the refrigerator and let the vial(s) warm up to room temperature.
2. Your 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 the medication is thoroughly cleaned.
5. If your doctor has prescribed any premedication or other supportive care for certain severe allergic symptoms, keep it nearby during your infusion.
6. Carefully follow your doctor's instructions and training if you have to administer the prescribed medicine for a severe allergic reaction.
7. Lay out the material
8. Wash hands and keep the area clean and germ-free while preparing the solution.

Insertion of needle into the vein

Instructions for your caregiver to insert needle into the vein for peripheral IV administration only (if a central venous access device is not available)

1. Ensure that the infusion system (infusion line connected to IV bag containing the medication) 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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06. Administration procedure

You, your home care nurse or caregiver should ensure that you have received training and understand the administrative logistics of home-infusion. During self-infusion, it is important that there is a carer or responsible adult nearby who is capable of acting according to the emergency plan

PLEASE NOTE: You should be prepared and readily available for home infusion prior to reconstitution, to avoid wastage of the medicinal product. Please refer to the **section 04** for further details of product preparation.

Reconstitution of the product

- Use aseptic technique.
- Prepare the medication as follows:

1. Your Physician will provide instructions on the number of vials to be reconstituted based on your weight and the prescribed dose.
2. Remove the required vials from the refrigerator. Reconstitute each vial using sterile water for injections:

Vial size	Water for injections
400 units	4.3 ml

3. Upon reconstitution, mix vials gently. **DO NOT SHAKE**.
4. Prior to dilution, visually inspect the solution in the vials. The solution should be clear to slightly opalescent and colourless. Do not use if the solution is discoloured, or if foreign particulate matter is present.

Dilution of the reconstituted product for intravenous administration

1. Withdraw the calculated volume of the medication from the appropriate number of vials. Some solution will remain in the vial

Vial size	Extractable volume
400 units	4.0 ml

2. Withdraw the calculated volume of velaglucerase alfa from the appropriate number of vials. Some solution will remain in the vial.
3. Dilute the total volume required in 100 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion. Mix gently. Do not shake. Initiate the infusion within 24 hours from the time of reconstitution.

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.

Setting up the infusion tubing

Velaglucerase alfa is intended for IV infusion only and should be administered over a period of 60 minutes. It 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 0.2 or 0.22 µm filter during administration.

1. Attach the IV tubing to the diluted bag of velaglucerase alfa and prime the IV tubing with normal saline solution, expelling all air.
2. Set the infusion rate to be administered over a period of 60 minutes.
3. If no central access is available, obtain peripheral IV access and attach the IV giving set. If no central access is available, obtain peripheral IV access and attach the IV giving set (**see section 04**) Follow local/facility protocols for IV insertion and infusion of medication.

Administer the medication

Instructions below refer to central and peripheral venous access administration. If you have a central venous access device (in-dwelling central line), you, your homecare nurse or caregiver should have been shown how to care for the device.

1. Insert the infusion line to the butterfly needle (**see section 04**) or to the patients in-dwelling central line as shown by the doctor or to the patients in-dwelling central line as shown by the doctor.
2. Attach the IV bag containing velaglucerase alfa to the drip stand and open the valve. Set the infusion rate determined by the treating physician.
3. Closely observe for any occurrence of IRRs (**see section 03**).
4. At the end of the infusion, to ensure that the total treatment dose is administered, rinse the tubing using a 50 ml 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 the medication 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 if an error 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 proceeding with another infusion.

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Next steps after the infusion

- At the end of the infusion, ensure that the roller clamp is closed, then remove your infusion bag and attach a flush bag as demonstrated by your healthcare professional. This ensures you receive all the medicine, including any left in the giving set. Once the flush bag is attached, open the roller clamp, allow some of the saline from the flush bag to infuse as instructed by your treating physician or treatment team, and then close the roller clamp.
- Place gauze over the needle site and slowly withdraw the needle/cannula, putting it in the sharps bin. Apply firm pressure to the exit site for around 3 minutes.
- **DO NOT** recap the IV needle set.
- Check that bleeding has stopped before applying a plaster. If the exit site continues to bleed after 5 minutes, re-apply firm pressure.
- After the infusion, dispose of sharps (needles or cannula) in the sharps bin.
- Remove your gloves and dispose of them. Wash your hands using the appropriate hand hygiene. Always clean your tray or work surface with warm soapy water, and rinse and dry after use.
- Do not dispose of the medicine via wastewater or household waste. Dispose of any unused medicine or waste material in accordance with local requirements.

Complete your Infusion Diary

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.

- At the end of your infusion, write down the following in your Infusion Diary:
  - Date and time (start and end) of infusion and note any interruptions.
  - Dose and site of infusion (to assist in rotating infusion sites).
  - Any side effects during or after each infusion.
  - Mark expiry date and batch/lot number, in the indicated ‘Batch/lot number and expiry date’ area
- Repeat this for each infusion.
- Start a new sheet when you run out of room on the sheet. When you are on your last remaining Infusion Diary sheets, ask your treatment clinic to provide a new Patient Guide (which includes an Infusion Diary).
- Report all side effects to your doctor.
- Keep each Infusion Diary for at least a year

Information on signs and symptoms related to IRRs

- If you are treated with velaglucerase alfa, you may experience side effects during or following the infusion.

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07. Emergency Plan

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

Should you experience a serious infusion related reaction, you should:

1. Stop the infusion	☐
2. Call the national emergency number	☐
3. Call the treating physician	☐

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08. Infusion Diary

The Infusion Diary should be completed and maintained by the treating physician, homecare nurse/patient/caregiver together in collaboration. Additional sheets for recording infusions will be included.

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 or 999

General Information

Administration Details

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

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Patient
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Address:
City:
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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 or 999

General Information

Administration Details

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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 or 999

General Information

Administration Details

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Telephone:
Email:
Nurse
Name:
Address:
City:
Telephone:
Email:
Pharmacy
Name:
Address:
City:
Telephone:
Email:
National Emergency Number
Telephone: 112 or 999

General Information

Administration Details

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Telephone:
Email:
Treating Physician
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Address:
City:
Telephone:
Email:
Nurse
Name:
Address:
City:
Telephone:
Email:
Pharmacy
Name:
Address:
City:
Telephone:
Email:
National Emergency Number
Telephone: 112 or 999

General Information

Administration Details

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Email:
Caregiver (if applicable)
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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 or 999

General Information

Administration Details

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First velaglucerase alfa infusion at home (DD/MM/YYYY):
velaglucerase alfa dose, frequency:
velaglucerase alfa infusion rate:
Indicate support to be provided by nurse:

This guide is intended for patients who have been prescribed velaglucerase alfa 400 Units powder for solution for infusion, and their caregivers and healthcare professionals (HCPs) who may assist them with home infusion.

This document has been approved by HPRA in June 2025

This guide is intended for use by Homecare Nurses / Patients / Caregivers only. This guide should be read together with the velaglucerase alfa Summary of Product Characteristics (SmPC) and package leaflet (PL).

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

08. Infusion Diary

The Infusion Diary should be completed and maintained by the treating physician, homecare nurse/patient/caregiver together 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 or 999

General Information

Administration Details

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

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Patient
Name:
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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 or 999

General Information

Administration Details

velaglucerase alfa administered since (DD/MM/YYYY):
First velaglucerase alfa infusion at home (DD/MM/YYYY):
velaglucerase alfa dose, frequency:
velaglucerase alfa infusion rate:
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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 or 999

General Information

Administration Details

velaglucerase alfa administered since (DD/MM/YYYY):
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velaglucerase alfa dose, frequency:
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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 or 999

General Information

Administration Details

velaglucerase alfa administered since (DD/MM/YYYY):
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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: