VPRIV®

[Velaglucerase alfa]

Velaglucerase alfa Treatment by Home Infusion

Guide for Physicians Treating Patients with Gaucher Disease

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

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).

In combination with the Patient/ Caregiver/ HCP Guide, this guide is intended to assist the treating physician or delegate, who is responsible for training patients/ caregivers on the identification of and measures to be taken in case of any adverse experiences such as infusion related reactions (IRRs) or medication errors that might occur associated with velaglucerase alfa home infusion. It reminds the treating physician of the importance of continuously monitoring patients receiving velaglucerase alfa and to emphasise to patients/ caregivers the importance of maintaining their Infusion Diary.

This document has been approved by HPRA in June 2025

This guide is intended for use by Physicians only, in conjunction with the velaglucerase alfa SmPC.

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01. Objectives of this guide

In combination with the homecare nurse/patient/caregiver guide, this guide is intended to assist the treating physician or delegate in reinforcing the following key information:

- Adequate training to patients/homecare nurses/caregivers on the method of preparation and administration of velaglucerase alfa.
- The patient eligibility checklist/screening to be performed
- Importance of educating patients/homecare nurses or caregivers about the associated risks **(Infusion related reactions (IRRs) including hypersensitivity reactions**), how to manage the possible complications and how to act in an emergency.
- Reminds you, the treating physician of the importance of continuously monitoring patients receiving velaglucerase alfa.
- Educate patients/homecare nurses/caregivers, to emphasise the importance of maintaining the Infusion Diary.

Please read the Summary of Product Characteristics (SmPC) in conjunction with this guide.

02. Patient eligibility for home infusion of velaglucerase alfa

Some patients with Type 1 Gaucher disease treated with 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 **at least three consecutive** well tolerated velaglucerase alfa infusions under medical supervision in a hospital, clinic or office setting to ensure satisfactory tolerance of the infusions. **Appropriate medical support, including personnel adequately trained in emergency measures, should be readily available when velaglucerase alfa is administered**.

Checklist to determine patient eligibility prior to initiation of home infusion:

Patient had at least three consecutive well-tolerated velaglucerase alfa infusions (no infusion-related reactions) in the hospital or clinic.	☐
Patient considered medically stable.	☐
History of adherence to infusion schedule.	☐
Patient has agreed to receive the medication for home infusion.	☐
The homecare nurse, patient and/or caregiver have been educated about home infusion, the associated risks, the possible complications, and the provision of medical assistance at home, including emergency contact details.	☐
The homecare nurse, patient and/or caregiver have been adequately trained in administering the infusion	☐
Confirm that the patient's home is safe (clean, hygienic, storage area for supplies, drug and emergency medication) and adequately equipped.	☐
Ensure that rapid and reliable communication measures have been established if problems occur.	☐
Ensure that the medications for pre-treatment, and/or treatment of IRRs are prescribed and readily available to mitigate any emergency, if necessary, and that the nurse/patient/caregiver knows how to utilize medications for pre-medication and/or treatment of serious IRRs when needed.	☐
The homecare nurse, patient and/or caregiver has received the educational materials intended for them.	☐

03. Training the homecare nurse/patient/caregiver for administration

Preparing the medication

1. Before the homecare nurse or patient/caregiver begins administration, ensure that the preparation area is thoroughly cleaned. The hands should be washed, the area kept clean and germ-free while preparing the solution.
2. The homecare nurse/patient/caregiver should 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)

velaglucerase alfa requires reconstitution and dilution and is intended for intravenous infusion only. It is for single use only and is administered through a 0.2 or 0.22 µm filter.

Aseptic technique must be used.

The medication has to be prepared as follows:

1. The number of vials to be reconstituted is determined based on the individual patient's weight and the prescribed dose.
2. The required vials are removed from the refrigerator. Each 400 Units vial is reconstituted with 4.3 ml of sterile water for injections.

Vial size	Water for injections
400 units	4.3 ml

3. Upon reconstitution, vials should be mixed gently. Vials should not be shaken. Each vial will contain an extractable volume of 4.0 ml (100 Units/ml).
4. Prior to dilution, the solution in the vials should be visually inspected; the solution should be clear to slightly opalescent and colourless; the solution should not be used if it is discoloured or if foreign particulate matter is present.

The calculated volume of medicinal product is withdrawn from the appropriate number of vials and the total volume required is diluted in 100 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion. The diluted solution should be mixed gently. It should not be shaken. The infusion should be initiated within 24 hours from the time of reconstitution. 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^{0}C

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Administration procedure

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 the medicinal product and prime the IV tubing with normal saline solution, expelling all air.
2. Set the infusion rate. The medication 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 medication remaining in the tubing is infused.
6. Remove the venous access device and discard in an infectious waste disposal container.

The Infusion Diary should include the infusion plan determined by the treating physician including dose and infusion rate as well as a record of the actual infusions administered including health status of the patient before, during and after infusion and measures taken in response to an adverse event.

Detailed description of the administration procedure

The administration procedure, dosage and infusion rate must be included in the Infusion Diary. Confirm that the homecare nurse/patient caregiver understands the administrative logistics of home infusion/self-administration of velaglucerase alfa.

04. Safety information

Monitor the patient for infusion-related reactions (IRRs), including allergic-type hypersensitivity

IRRs are defined as any adverse drug reaction occurring within 24 hours after the initiation of velaglucerase alfa infusion.

Most side effects, including allergic reactions, occurred during the infusion or shortly after. The most frequently reported symptoms of hypersensitivity include **headache, dizziness, fever/body temperature increased, back pain, joint pain and tiredness, as well as high blood pressure, blurry vision, and vomiting (uncommonly reported).** Some patients experienced 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), also an allergic skin reaction such as hives, severe rash or itching** can occur.

The majority of IRRs occur within the first 6 months of treatment. If the patient experiences a reaction suggestive of hypersensitivity, they should be told to notify the prescribing physician immediately.

Instruct homecare nurse/patient/caregiver on managing infusion-related reactions

If a serious infusion-related reaction occurs, including anaphylaxis, discontinue the infusion immediately if it occurs during administration. Management of infusion-related reactions should 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 in case of serious IRRs 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, consider prescribing an antihistamine and/or corticosteroid before the infusion to help prevent an allergic reaction from happening.

Emphasize the need to communicate any events to you, the treating physician.

In the event of an infusion-related reaction or hypersensitivity, the homecare nurse/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.

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.

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05. Emergency Plan

Necessary actions in the event of a serious infusion reaction, hypersensitivity reaction and/or adverse reaction:

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

Remind the homecare nurse, patient/caregiver to:

1. Stop the infusion	☐
2. Call the treating physician	☐
3. Follow the individual instruction provided above	☐

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