Cerezyme®
Imiglucerase

CEREZYME® (IMIGLUCERASE)

CEREZYME® HOME INFUSION GUIDE FOR HEALTHCARE PROFESSIONALS (HCPs)

Version 1.1 May 2025

This guide is not intended to suggest or recommend home infusion therapy for any patient. The decision to provide treatment in the home setting is made by the treating physician, who knows the patient's current clinical status and previous infusion history, in consultation with the patient and/or his/her caregiver. This guide is solely to share information that might be helpful to HCPs and their patients/caregivers when treated at home.

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1. OBJECTIVES AND GOALS

The objective of this home infusion guide is to provide information and guidance to healthcare professionals (HCPs) for the management of patients receiving Cerezyme® in the home setting and to mitigate the following risks:

- Infusion-associated reactions (IARs) including hypersensitivity
- Infusion site reactions
- Medication errors in the home infusion setting.

This guide covers patient evaluation and selection, discussion of requirements for, and organisation of the home infusion.

Cerezyme® is an enzyme replacement therapy (ERT) available to treat patients who have a confirmed diagnosis of Type 1 or Type 3 Gaucher disease, who show signs of the disease and is generally well tolerated. To enhance convenience and improve patient's quality of life, ERT infusions may be transferred to the patient's home if specific requirements can be fulfilled. This increases comfort and flexibility of infusion schedule.

The decision to transfer Cerezyme® treatment to the patient's home setting is made by the treating physician and should take into account patient preferences and medical status.

The home infusion will take place under the responsibility of the treating physician.

It is the responsibility of the treating physician to provide the 'Cerezyme® home infusion guide for patients and their caregivers' to the patient/carer if the patient is eligible for home infusion treatment.

It is the responsibility of the treating physician to ensure safe administration of Cerezyme®, to reduce and mitigate the risks of medication errors in the home and IARs, including hypersensitivity reactions.

The processes presented in this guide serve as overall guidance but are subject to local medical practice and national rules and regulations.

2. INFORMATION FOR HCPs PRESCRIBING CEREZYME®

2.1. Assessing patient eligibility for home infusion

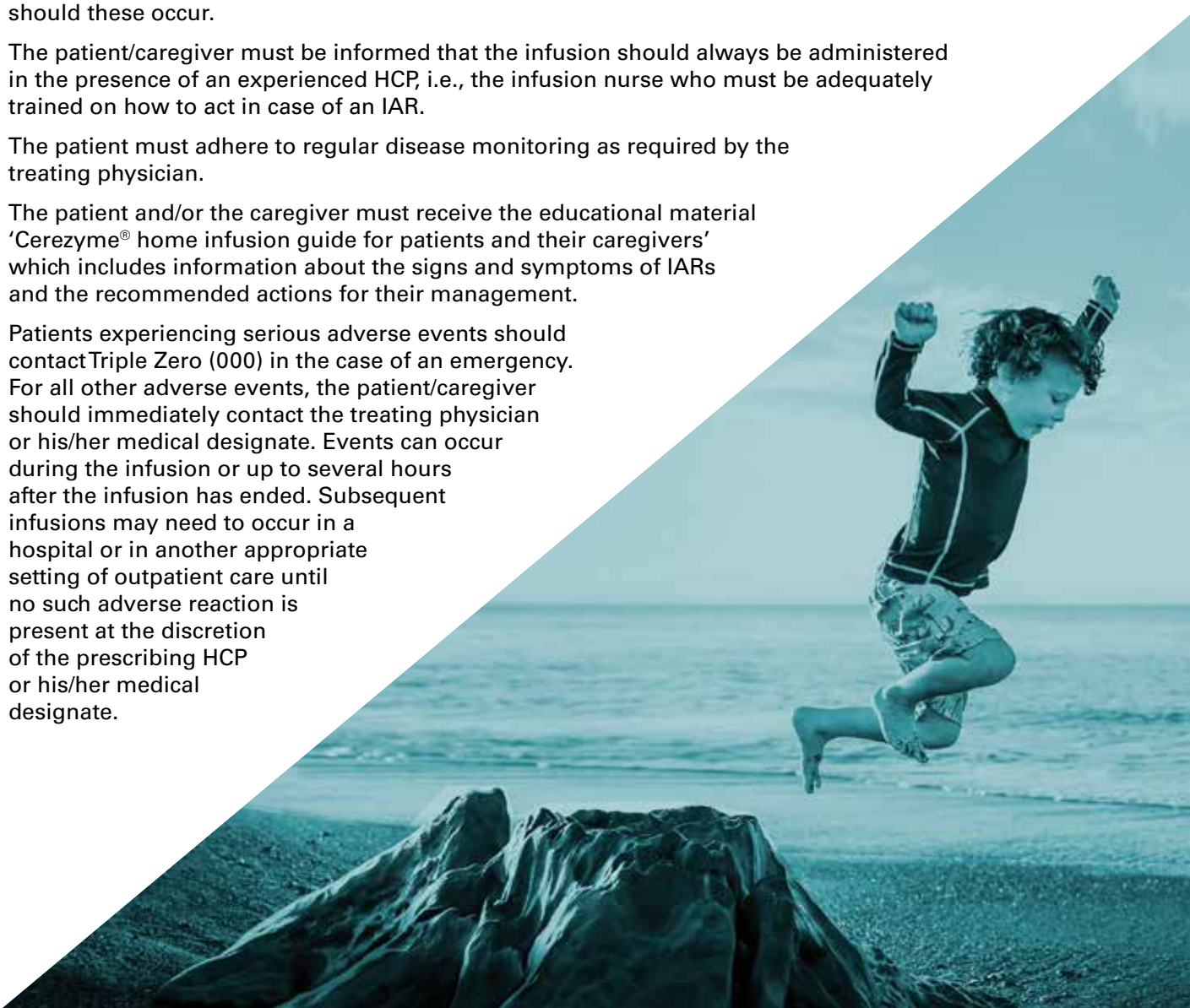
Before making any arrangements for providing Cerezyme® infusion at home, the treating physician overseeing the patient's clinical care must determine if the patient fulfils the following primary criteria for transfer of hospital-based infusion therapy to the patient's home setting:

- Patients should be considered medically stable. An evaluation should be completed prior to transition.
- Patients should have received Cerezyme® infusions in a controlled setting for several months until there is a documented pattern of well tolerated infusions with no IARs or mild IARs that have been controlled with pre-medication.
- Patients should have a history of adherence to the prescribed infusion schedule.
- Regular disease monitoring of the home-infused patient is the responsibility of the treating physician.

2.2. Requirements and organisation of home infusion

Once the patient has been considered to be eligible for home infusion based on the primary criteria, a set of requirements must be considered to ensure that Cerezyme® infusions can be safely, efficiently, and reliably delivered at the patient's home:

- The patient and/or caregiver, and/or homecare agency have been informed by the treating physician about the treatment to be provided at home, the associated risks, the possible complications, and the provision of medical assistance at home.
- The patient and/or caregiver must agree to the treatment at home.
- The home environment must be conducive for home infusion therapy including a clean environment with electricity, water, telephone access, refrigeration, and physical space to support storage of Cerezyme® and other infusion supplies.
- The infusion rate of Cerezyme® that was tolerated by the patient in a more controlled setting (e.g., in the hospital or outpatient setting) should not be changed in the home setting unless necessary due to safety considerations.
- Appropriate scheduling and monitoring of the infusion are the responsibility of the treating physician/infusion nurse.
- The patient must be physically and mentally able to undergo the infusions at home. The treating physician is responsible for the recommendation to receive Cerezyme® infusions at home.
- The patient has venous access or a central venous access device that allows adequate infusion.
- The patient and/or caregiver(s) understand the illness and can recognise adverse events such as hypersensitivity reactions and medication errors and understand the procedure to be followed should these occur.
- The patient/caregiver must be informed that the infusion should always be administered in the presence of an experienced HCP, i.e., the infusion nurse who must be adequately trained on how to act in case of an IAR.
- The patient must adhere to regular disease monitoring as required by the treating physician.
- The patient and/or the caregiver must receive the educational material 'Cerezyme® home infusion guide for patients and their caregivers' which includes information about the signs and symptoms of IARs and the recommended actions for their management.
- Patients experiencing serious adverse events should contact Triple Zero (000) in the case of an emergency. For all other adverse events, the patient/caregiver should immediately contact the treating physician or his/her medical designate. Events can occur during the infusion or up to several hours after the infusion has ended. Subsequent infusions may need to occur in a hospital or in another appropriate setting of outpatient care until no such adverse reaction is present at the discretion of the prescribing HCP or his/her medical designate.



3. RESPONSIBILITIES OF HCPs PRESCRIBING CEREZYME®

- The treating physician is responsible for the initiation of all necessary administrative actions, allowing other stakeholders (pharmacy, infusion nurse, patient, caregiver) to proceed.
- The treating physician has informed patient and/or caregiver(s) about the disease, treatment and home infusion procedure and has distributed to the patient/caregiver the educational material 'Cerezyme® home infusion guide for patients and their caregivers'. Distribution is only required where the treating physician decides that the patient is eligible for home infusion treatment.
- The treating physician is responsible for the selection of the infusion rate and dose. The infusion rate of Cerezyme® that was tolerated by the patient in a more controlled setting (e.g., in the hospital or other medical setting) must not be changed in the home setting, unless necessary due to safety considerations. Any changes in Cerezyme® administration must be clearly documented.
- The home infusion will take place under the responsibility of the treating physician.
- It is the responsibility of the treating physician to ensure safe administration to the patient to avoid risks of medication errors and hypersensitivity reactions.
- Pre-infusion treatment, if administered in the hospital or other medical setting (e.g. antihistamines, paracetamol, ibuprofen, corticosteroids), must be provided based on the patient- specific prescription. This treatment must not be altered in the home setting, unless medically warranted at the discretion of the treating physician.
- Emergency treatment must be provided based on the patient-specific prescription instructions and a documented emergency plan must be given to the infusion nurse prior to setting up home infusion.
- The treating physician must ensure that a rapid and reliable line of communication is available to expedite an emergency response in case immediate medical attention is required.
- Patients experiencing adverse events need to contact the treating physician or his/her medical designate immediately. Subsequent infusions may need to occur in a hospital or other medical setting at the discretion of the treating physician or his/her medical designate.
- Regular disease monitoring of the home-infused patient is the responsibility of the treating physician.
- The treating physician is strongly encouraged to report any adverse events that occur during treatment with Cerezyme®. To report an adverse event, refer to Section 5 'Safety Reporting'.

4. INFORMATION REGARDING THE ADMINISTRATION OF CEREZYME®

Instructions for use relating to the dose and method of administration for Cerezyme® are detailed in the Cerezyme® Product Information (PI), available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swccerez) or alternatively via the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) at: (https://www.tga.gov.au/resources/artg), or the Package Insert in the Cerezyme® vial box. Further important information to be read in combination with the Cerezyme® PI/package insert is detailed in the sections below.

4.1. Responsibilities of infusion nurse

- The infusion nurse will have a coordinating role alongside the treating physician and the patient and/or caregiver(s) in organising the treatment at home, and will establish with the treating physician, patient and/or caregiver(s) the level of support necessary in the home.
- The infusion nurse is qualified to give intravenous (IV) infusions, has been trained on Cerezyme® and is aware of the possible adverse events and the actions to be taken should they occur.

- The infusion nurse will strictly follow the prescribed dose and method of administration of Cerezyme® as stated by the prescribing physician.
- The infusion nurse documents each administration of Cerezyme®.
- Appropriate scheduling and monitoring of the infusions is the responsibility of the treating physician and infusion nurse.
- In the event of an IAR, the infusion nurse should discontinue the infusion and phone the treating physician and/or Triple Zero (000). The treating physician and/or or Triple Zero (000) must also be phoned if an IAR occurs shortly after completion of the infusion. Reporting of adverse events helps ensure the ongoing safety of Cerezyme®. To report an adverse event, refer to Section 5 'Safety Reporting'.

4.2. Pre-treatment and emergency treatment

- Appropriate pre-treatment should be provided based on the patient-specific prescription. Treatment administered in the hospital/clinic setting should not be altered in the home setting unless medically warranted at the discretion of the treating physician.
- Medications must be available to respond to an emergency if necessary.
- In the event the patient experiences an adverse event like hypersensitivity reactions during or shortly after the infusion, the infusion should be discontinued immediately and the treating physician or his/her medical designate should be contacted to seek advice. Subsequent infusions may need to occur in a hospital or other medical setting.

4.3. Prescription

The Cerezyme® dose, required reconstituted volume, infusion rate, premedication, emergency medication, as well as any changes will be determined by the treating physician. Any changes of this prescription (dose or infusion rate) must be documented.

4.4. Required Supplies

Supplies are generally provided by the hospital/pharmacy to the patient or to a third party with the appropriate prescription:

- Vials of Cerezyme®(400 U per vial); must be stored at a temperature of between 2°C and 8°C.
- Infusion materials
    - o Infusion lines, syringes, needles, compresses, antiseptics, etc.
    - o NaCl 0.9% solution and sterile water
        - NaCl 0.9% solution, 2 x 100 mL, or 1 x 250 ml for IV administration
        - NaCl 0.9% solution, 2 x 50 mL to flush infusion line pre- and post-infusion
- Chlorhexidine 0.5% in alcohol 70% (antiseptic solution)
- Appropriate number of 10 mL and 50 mL syringes depending upon dose of Cerezyme®
- 3 x sterile hypodermic needles (1.1 x 40 mm)
- 1 x butterfly needle
- In-line low protein-binding 0.2 µm filter
- Hypodermic needle tray
- Micropore tape
- Mediswabs
- Sharps bin
- Hand wash
- Additional requisites if using a venous access device.

- Heparin
- Needles for heparin
- Dressing pack
- Sterile gloves

- Emergency medication (antihistamines and/or corticosteroids)

4.5. Dose and method of administration

Information on dose and method of administration for Cerezyme® are extensively detailed in the Cerezyme® PI, available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swccerez) or alternatively via the TGA ARTG at: (https://www.tga.gov.au/resources/artg), or the Package Insert in the Cerezyme® vial box. Further important information to be read in combination with the Cerezyme® PI/Package Insert is detailed below.

After reconstitution with water for injection and dilution with 0.9% sodium chloride intravenous solution the preparation is administered by intravenous infusion over 1 to 2 hours.

Dosage should be individualised for each patient. Initial dosages range from 2.5 U/kg of body weight 3 times a week to 60 U/kg once every two weeks. 60 U/kg every 2 weeks is the dosage for which most data are available. Disease severity may dictate that treatment be initiated at a relatively high dose or relatively frequent administration. Dosage adjustments should be made on an individual basis, and may increase or decrease, based on achievement of therapeutic goals as assessed by routine comprehensive evaluations of the patient's clinical manifestations.

Initial doses of 60 U/kg of body weight once every 2 weeks have shown improvement in haematological and visceral parameters within 6 months of therapy, and continued use has either stopped progression of or improved bone disease. Administration of doses as low as 15 U/kg of body weight once every 2 weeks has been shown to improve haematological parameters and organomegaly, but not bone parameters.

Method of administration Preparation and administration instructions: Use aseptic techniques.

The lyophilised powder should be reconstituted with water for injection, diluted with 0.9% sodium chloride intravenous solution and then administered by intravenous infusion. It is recommended that the diluted solution be filtered through an in-line low protein-binding 0.2 µm filter during administration.

1. Determine the number of vials to be reconstituted based on the individual patient's dosage regimen and remove the vials from the refrigerator.
   Occasionally, small dosage adjustments may be made to avoid discarding partially used vials. Dosages may be rounded to the nearest full vial as long as the monthly administered dosage remains substantially unaltered.
2. Reconstitute each vial with water for injection. The final concentrations and administration volumes are provided in **Table 1:**

Table 1. 400 Unit Vial Concentration and Administration Volume

	400 Unit Vial
Sterile water for reconstitution	10.2 mL
Final volume of reconstituted product	10.6 mL
Concentration after reconstitution	40 U/mL
Withdrawal volume	10.0 mL
Units of enzyme within final volume	400 Units

Avoid forceful impact of water for injection on the powder and, by mixing gently, avoid foaming of the solution. The pH of the reconstituted solution is approximately 6.1.

3. Before further dilution, visually inspect the reconstituted solution in each vial for foreign particles and discolouration. Do not use vials exhibiting foreign particles or discolouration. Do not use Cerezyme® after the expiration date on the vial.

Cerezyme® contains no preservatives or antimicrobial agent. Use once and discard any residue. Any unused reconstituted solution must be discarded appropriately.

The reconstituted solution contains 40 Units imiglucerase per mL. The reconstituted volume allows accurate withdrawal of a nominal volume of 10.0 mL for the 400 Unit vial.

Withdraw the reconstituted solution from each of the reconstituted vials and dilute with 0.9% Sodium Chloride intravenous solution to a total volume of 100 to 200 mL. Mix the infusion solution gently. Being a protein solution, slight flocculation (described as thin translucent fibers) occurs occasionally after dilution. The diluted solution may be filtered through an in-line low protein-binding 0.2 µm filter during administration.

It is recommended that the diluted solution be administered within 3 hours. The product diluted in 0.9% sodium chloride intravenous solution will retain chemical stability if stored for up to 24 hours between 2° and 8°C, protected from light, but microbial safety will depend on the reconstitution and dilution having been performed aseptically.

5. CEREZYME® SAFETY PROFILE

Identified risks of treatment with Cerezyme® include:

- Infusion-associated reactions (IARs) including hypersensitivity
- Infusion site reactions
- Medication errors in the home infusion setting

Approximately 15% of patients treated with Cerezyme® develop immunoglobulin G (IgG) antibodies to imiglucerase during the first year of therapy. Patients who develop IgG antibody are most likely to do so within 6 months of treatment and will rarely develop antibodies to Cerezyme® after 12 months of therapy. Patients with antibody to imiglucerase have a higher risk of hypersensitivity reactions. Conversely, not all patients with symptoms of hypersensitivity have detectable IgG antibody. If a patient experiences a reaction suggestive of hypersensitivity, subsequent testing for imiglucerase antibodies is advised.

Treatment with Cerezyme® should be approached with caution in patients who have exhibited symptoms of hypersensitivity to the product. Symptoms suggestive of hypersensitivity occurring during, or shortly after, infusions include rash, pruritis, flushing, urticaria, angioedema, chest discomfort, tachycardia, cyanosis, dyspnea, coughing, paraesthesia, backache, and hypotension.

The infusion should be discontinued immediately if these symptoms occur, and the Infusion nurse should contact the patient's treating physician. Most patients have successfully continued therapy after a reduction in rate of infusion and pre-treatment with antihistamines and/or corticosteroids.

Information relating to the full safety profile of Cerezyme® can be found in the PI, available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swccerez) or alternatively via the TGA ARTG at: (https://www.

tga.gov.au/resources/artg).

6. SAFETY REPORTING

To report adverse event(s) and/or pregnancy occurring in association with the use of Cerezyme®:

Please contact Sanofi Medical Information*:

Phone: 1800 818 806 (Australia)

Fax: 1800 053 105 (Australia)

E-mail: MedInfo.Australia@sanofi.com
*or refer to the Patient Support Program specific Pharmacovigilance reporting requirements for PSP nurses.

Alternately, you may report adverse events and/or pregnancy directly to the Therapeutic Goods Administration (TGA)

TGA (Australia)

Phone: 1800 044 114

Fax: +61 2 6232 8392

E-mail: adr.reports@tga.gov.au

Online reporting at: https://aems.tga.gov.au

7. FURTHER INFORMATION

Please refer to the Cerezyme® PI available at Sanofi (https://qr.medsinfo.com.au/tx/sw.cfm?h=swccerez) or alternatively via the TGA ARTG at: (https://www.tga.gov.au/resources/artg) for complete indication statements and further information about the approved use of Cerezyme®.

Cerezyme® PI

MAT-AU-2502510-1.0 - 12/2025.