

HEALTH CARE PROFESSIONAL RECONSTITUTION GUIDE **FOR CEREZYME® 400**[1]

Treatment for Gaucher Disease



Step 2: preparation of the equipment

PREPARATION

1. The vials should be stored in a refrigerator at a temperature between 2°C and 8°C.
2. Prepare the equipment:

- The number of vials of Cerezyme® 400 required is determined based on the patient's weight.
  Each vial contains 400 units of imiglucerase per 10mL (40 U/mL).
  Approximately 30 minutes before preparation, the vials should be removed from the refrigerator to reach room temperature. Check the expiry date printed on the bottom of the vial pack (do not use Cerezyme® after the expiry date).
  Sterile water for injections (10.2 mL per vial) is required to reconstitute Cerezyme®
- NaCl 0.9% solution, 100 - 200 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, 20 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 micron filter
- Hypodermic needle tray; Micropore tape; Mediswabs; Sharps bin; Handwash

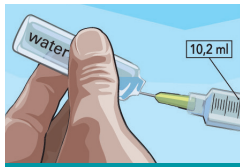
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Cerezyme® imiglucerase

RECONSTITUTION USING STERILE WATER



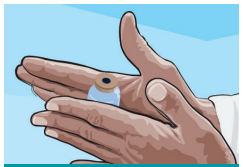
Step 4: observe aseptic technique



Step 6: drawing of sterile water



Step 7: injection of sterile water



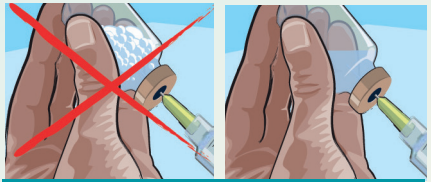
Step 8: carefully swirl the vial using a circular movement of the hands

3. Remove the flip-off cap from the Cerezyme® vial.
4. Disinfect the rubber stopper of the Cerezyme® vial with chlorhexidine and allow to air dry
5. Open the sterile water for injections
6. Draw the required number of mL of sterile water for injections into the syringe: 10.2 mL for each 400 U vial.
7. Inject the water gently to the inside wall of each vial of Cerezyme® (avoid forceful impact of water for injections on the powder).
8. Carefully swirl the vial(s) to mix the solution (avoid forceful shaking during the reconstitution process to avoid foaming of the solution).
9. Small bubbles may appear after the gentle mixing.
10. Let the solution settle for a few minutes to allow any bubbles present to disappear and to ensure that the powder is properly reconstituted (check that there are no foreign particles or discolouration).
11. The reconstituted volume allows accurate withdrawal of 10,0 mL (equal to 400 units) from each vial.

DILUTION IN 0.9% NACL



Step 13: Calculate the quantity of reconstituted Cerezyme® solution present in the vials and draw the same quantity from the bag of NaCl solution, thus creating enough space to add the reconstituted Cerezyme® solution.



Step 14: at the time of drawing, the reconstituted product should not contain any foam

12. Disinfect the cap/opening of the NaCl 0.9% solution bag using chlorhexidine and allow to air dry.
13. Calculate the quantity of reconstituted Cerezyme® solution present in the vials and draw the same quantity from the bag of NaCl solution, thus creating enough space to add the reconstituted Cerezyme® solution.
    For instance, if the prescribed quantity is 7 vials of Cerezyme® of 400 units each, remove 70 mL (=7 x 10 mL) of NaCl solution from the bag of NaCl solution.
    Never remove more than half the content of the bag of NaCl to ensure that at least half the diluted solution consists of NaCl.
14. Using one or more 20 or 50 mL syringes, withdraw 10 mL from each of the reconstituted Cerezyme® vials and combine the withdrawn volumes. At the point when these quantities are withdrawn, the reconstituted product should not contain any foam.
15. Gently inject the total volume of the reconstituted Cerezyme® solution into the bag of NaCl 0.9% solution.
16. Gently rotate, invert or massage the infusion bag. Do not shake the solution.
17. The appropriate amount of Cerezyme® for each patient is diluted with 0,9 % sodium chloride injection solution, to a final volume of 100 – 200 mL.
18. The diluted solution should be filtered through an in-line low protein-binding 0.2 micron filter during administration.

ADMINISTRATION

19. The Cerezyme® dose and infusion rate will be determined by the treating doctor.
20. Cerezyme® must be administered by intravenous infusion.
21. Do not infuse CEREZYME® in the same IV line with other products.
22. The solution must be administered within three hours of dilution.
23. 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.
24. In light of microbiological safety, the diluted preparation should be used immediately. If the preparation cannot be used immediately, the product will retain chemical stability if stored between 2°C and 8°C, away from light, for a maximum period of 24 hours.

UNDESIRABLE EFFECTS

- Undesirable effects have been reported which are related to the route of administration: infusion site discomfort, pruritus, burning, swelling or sterile abscess at the site of venipuncture.
- Symptoms suggestive of hypersensitivity have been noted in approximately 6,6% of the patients. Onset of such symptoms has occurred during or shortly after infusions. These symptoms generally respond to treatment. Patients should be advised to contact their doctor immediately if these or other symptoms occur.
- Not all the undesirable effects have been listed. Please refer to the Professional Information for further details.
- Report non-serious and serious adverse events to the Sanofi Pharmacovigilance department at ZA.Drugsafety@sanofi.com or 011 256 3700. Adverse events considered serious must be reported to Sanofi as soon as possible and at the latest within one business day.

HOME TREATMENT

- The home environment must be conducive to home infusion therapy including a clean environment with electricity, water, telephone access, refrigeration, and physical space to support storage of Cerezyme® vials and other infusion supplies.
- It is preferable for a caregiver/third party to be present with the patient.
- The patient and/or caregiver have been adequately trained in the procedures of Cerezyme® reconstitution, dilution and infusion.

(1) The use of Cerezyme® (imiglucerase) is indicated for long-term enzyme replacement therapy for paediatric and adult patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease who exhibit clinically significant non-neurological manifestations of the disease. The non-neurological manifestations of Gaucher disease include one or more of the following conditions: anaemia, after exclusion of other causes such as iron deficiency; thrombocytopenia; bone disease, after exclusion of other causes such as Vitamin D deficiency; hepatomegaly or splenomegaly.

References: 1. CEREZYME® Professional Information. August 2022. **2.** CEREZYME® Professional Information. August 2022.

For full prescribing information refer to the professional information approved by the medicines regulatory authority.

SOUTH AFRICA: S4 **CEREZYME® 400** (powder for concentrate for solution for infusion)
QUALITATIVE AND QUANTITATIVE COMPOSITION: Each reconstituted vial contains 400 units imiglucerase per 10 mL (40 U/mL).
REGISTRATION NUMBER: 36/31/0179.
NAMIBIA: NS2 **CEREZYME® 400** (powder for concentrate for solution for infusion)
QUALITATIVE AND QUANTITATIVE COMPOSITION: Each reconstituted vial contains 400 units imiglucerase per 10 mL (40 U/mL).
REGISTRATION NUMBER: 14/31/0064.
HOLDER OF CERTIFICATE OF REGISTRATION: sanofi-aventis south africa (pty) ltd., Reg. no.: 1996/010381/07, Floor 5, Building I, Hertford Office Park, 90 Bekker Road, Midrand, 2196.Tel: (011) 256 3700.
MAT-ZA-2300898-1.0-05/2024

Cerezyme®
imiglucerase

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