SANOFI GENZYME HOME ASSISTANCE

CEREZYME Home Infusion HCP reconstitution Guide

This additional risk minimization are approved by SFDA

V2-JAN 2021

SANOFI GENZYME

Health Care Professional Reconstitution Guide for Cerezyme® [1]

– Treatment for Gaucher Disease –

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 required is determined based on the patient's weight. Each vial contains 400 units of imiglucerase. 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 to reconstitute Cerezyme
- 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 micron filter
- Hypodermic needle tray; Micropore tape; Mediswabs; Sharps bin; Handwash

Reconstitution using sterile water

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 400 U vials.

7. Inject the sterile water gently down the glass side of each vial.

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 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).

Dilution in 0.9% NaCl

11. Disinfect the cap/opening of 1 or 2 bags of NaCl 0.9% solution using chlorhexidine and allow to air dry.

12. 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 3 vials of Cerezyme® of 400 units each, remove 30 ml (= 3 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

13. Using one or more 50 ml syringes, draw 10 ml (400 U vial) from the reconstituted vials. When these quantities are drawn, the reconstituted product should not contain any foam. Gently inject the total volume of the reconstituted Cerezyme solution into the bag of NaCl 0.9% solution.

14. Carefully mix this Cerezyme solution.

15. The diluted solution should be filtered through an in-line low protein-binding 0.2 micron filter during administration.

Administration

16. The Cerezyme dose and infusion rate will be determined by the treating physician.

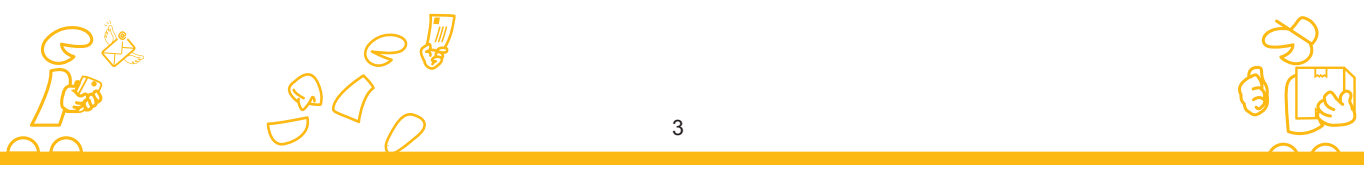
17. Cerezyme must be administered by intravenous infusion.

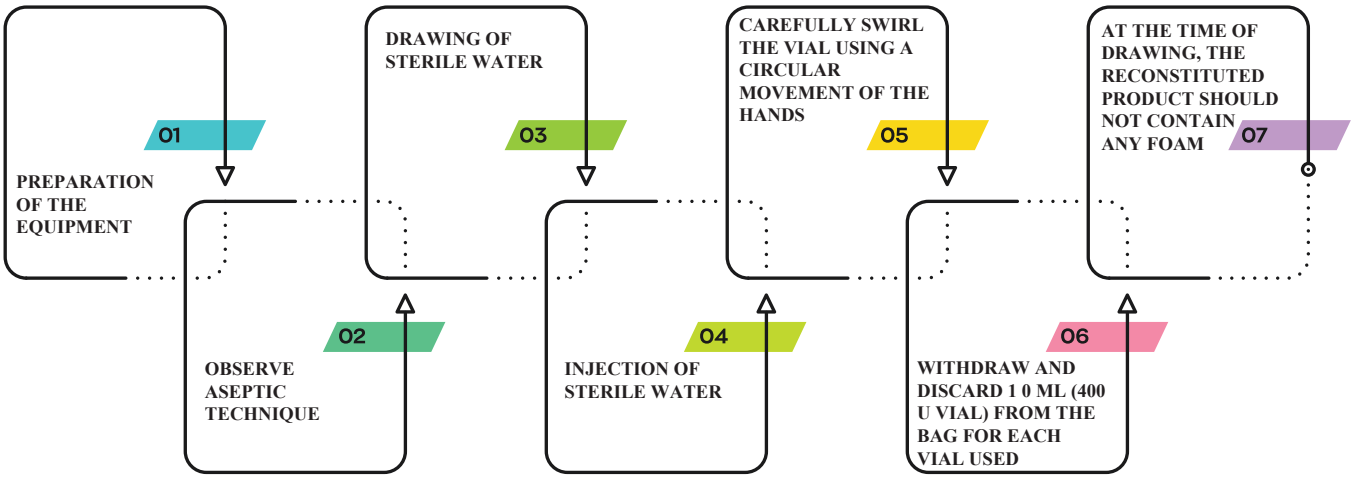
18. The solution must be administered within **three hours** of reconstitution.

19. Prior to infusion start, fill the infusion system with the mixed solution; fill the entire system to remove any air bubbles that may be present.

20. 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.

21. In light of microbiological safety, the preparation should be used immediately. If the preparation cannot be used immediately, it may be kept in a refrigerator between 2°C and 8°C, away from light, for a maximum period of 24 hours.





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 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 and infusion.
- A portable infusion system like a portable diffuser may be used (positive pressure infusion system).

Adverse events

- In a small number of patients adverse events have been reported which are related to the route of administration: discomfort, pruritus, burning, swelling or sterile abscess at the site of venipuncture.
- Symptoms suggestive of hypersensitivity have been noted in approximately 3% of the patients. Onset of such symptoms has occurred during or shortly after infusions; these have included pruritus, flushing, urticaria/angioedema, chest discomfort, tachycardia, cyanosis, respiratory symptoms, paraesthesia, and backache. Hypotension associated with hypersensitivity has also been reported rarely. These symptoms generally respond to treatment with antihistamines and/or corticosteroids. **The infusion should be discontinued immediately if these symptoms occur**.

(1) The use of Cerezyme® (imiglucerase) is indicated for use as a long-term enzyme replacement therapy in 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 all other causes such as iron deficiency; thrombocytopenia; bone disease, after exclusion of all other causes such as Vitamin D deficiency; hepatomegaly or splenomegaly.

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