PACKAGE INSERT – Fabrazyme – Powder for injection vial

NAME OF THE MEDICINE

Fabrazyme, agalsidase beta-rch

DOSAGE FORM

Powder for injection for intravenous infusion

HOME INFUSION

A Home Infusion Guide for HCPs and Patients/Carers is available to provide home infusion information related to Fabrazyme: https://qr.medsinfo.com.au/tx/sw.cfm?h=swcfabra

METHOD OF PREPARATION

Preparation:

1. Determine the number of vials for reconstitution based on the patient's body weight (kg) and the recommended dose of 1 mg/kg.
2. Using aseptic technique, reconstitute each vial with Sterile Water for Injection to yield a 5 mg/mL clear, colourless solution. The final concentration and administration volumes are provided in Table 1 below:

Table 1 - Final Concentration and Administration Volumes

	5 mg Presentation	**35 mg Presentation**
Sterile water for reconstitution	1.1 mL	7.2 mL
Final volume of reconstituted product	1.1 mL	7.4 mL
Concentration after reconstitution	5 mg/mL	5 mg/mL
Extractable volume	1.0 mL	7.0 mL
Amount (mg) of enzyme within extractable volume	5 mg	35 mg

3. Visually inspect the reconstituted vials for particulate matter and discolouration. Do not use vials exhibiting particulate matter or discolouration. Fabrazyme does not contain preservatives. Vials are for single use only.
4. Immediately withdraw reconstituted solution from each vial, and using aseptic technique, further dilute with 0.9% Sodium Chloride for Injection to a total volume based on the individual dose dispensed (see Table 2 below). Total infusion volumes as low as 50 mL were used in the Phase 1/2 trial.

Table 2 - Minimum Total Volume for Infusion Based on Individual Dose

Individual Patient Dose Dispensed (mg)	**Minimum Total Volume**
<35	50
35.1 to 70	100
70.1 to 100	250
>100	500

5. Administer the solution intravenously at an initial rate of no more than 0.25 mg/min. The diluted solution may be filtered through an in-line low protein-binding 0.2 µm filter during administration.

Compatibility:

Fabrazyme should not be infused in the same intravenous line with other products.

IN-USE STORAGE CONDITIONS

Fabrazyme does not contain any preservatives; therefore after dilution with saline in the infusion bag, the unused product should be discarded.

To reduce microbiological hazard, use as soon as practicable after reconstitution/dilution.

Fabrazyme diluted for infusion in 0.9% Sodium Chloride for Injection is stable for up to 24 hours when stored at 2°C

to 8°C (36°F to 46°F), without microbial contamination. The diluted solution may be filtered through an in-line low protein-binding 0.2 µm filter during administration.

SPONSOR

sanofi-aventis australia pty ltd
International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000
Phone: 1800 818 806
Email: medinfo.australia@sanofi.com

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