PACKAGE INSERT – Cerezyme – Powder for solution for infusion

NAME OF THE MEDICINE

Imiglucerase-rch

DOSAGE FORM

Powder for solution for infusion

HOME INFUSION

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

METHOD OF PREPARATION

Preparation:

Use Aseptic Techniques

The lyophilised powder has to 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 0.2µm 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	40U/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.

   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.

Compatibility:

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

IN-USE STORAGE CONDITIONS

It is recommended that the diluted solution be administered within 3 hours.

If necessary, the product diluted in 0.9% Sodium Chloride intravenous solution can be stored for up to 24 hours between 2° - 8°C, protected from light, but microbiological safety will depend on the reconstitution and dilution

having been performed aseptically.

Cerezyme, after reconstitution, has been shown to be stable for up to 12 hours when stored at room temperature (25°C) and at 2° - 8°C. Cerezyme, when diluted, has been shown to be stable for up to 24 hours when stored at 2° - 8°C. After reconstitution, promptly dilute vials and do not store for subsequent use.

SPONSOR

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