

PACKAGE INSERT – Aldurazyme – Concentrate for solution for injection

NAME OF THE MEDICINE

Laronidase -rch

DOSAGE FORM

Injection vial for intravenous infusion

HOME INFUSION

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

METHOD OF PREPARATION

Preparation:

The Aldurazyme solution should not be shaken, as this may cause a decrease in the potency of the product.

1. Prepare an infusion bag of 0.9% Sodium Chloride for Injection. Determine the total volume of the infusion to be used based on the patient's body weight. The total final volume should be either 100 mL (if weight is less than or equal to 20 kg) or 250 mL (if weight is greater than 20 kg).
2. Determine the number of vials to be diluted based on the individual patient's weight and the recommended dose of 100 U/kg. Remove the required number of vials from the refrigerator to allow them to reach room temperature. Do not heat or microwave vials.
3. Before dilution, visually inspect each vial for particulate matter and discolouration. The Aldurazyme solution should be clear to slightly opalescent and colourless to pale yellow. A few translucent particles may be present. Do not use if the solution is discoloured.
4. Withdraw and discard a volume of the 0.9% Sodium Chloride for Injection from the infusion bag, equal to the volume of Aldurazyme concentrate to be added.
5. Slowly withdraw the calculated volume of Aldurazyme (laronidase) from the appropriate number of vials, using caution to avoid excessive agitation.
6. Slowly add the Aldurazyme solution to the 0.9% Sodium Chloride for Injection, using care to avoid agitation of the solutions.
7. Gently rotate the infusion bag to ensure proper distribution of Aldurazyme. Prior to use, visually inspect the solution for particulate matter. Only clear and colourless solutions, practically free of visible particles, should be used. Do not shake the solution.
8. It is recommended that the diluted solution be filtered through an in-line low protein-binding 0.2µm filter during administration.

Compatibility:

Aldurazyme must not be mixed with other medicinal products in the same infusion.

IN-USE STORAGE CONDITIONS

The diluted solution should be used immediately. If not used immediately, in-use storage and conditions prior to use are the responsibility of the user and should not be longer than 24 hours when refrigerated (2°C to 8°C)

SPONSOR

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