PACKAGE INSERT – Elaprase – Solution for IV infusion vial

NAME OF THE MEDICINE

Idursulfase

DOSAGE FORM

Solution for IV infusion vial

METHOD OF PREPARATION

Preparation:

ELAPRASE is a concentrated solution for intravenous infusion and must be diluted in 100 mL of 0.9% Sodium Chloride for Injection. Each vial of ELAPRASE contains 3 mL (6 mg) of idursulfase. Vials are for single use only. Use of an infusion set equipped with a 0.2 micrometer (µm) filter is recommended.

Use Aseptic Techniques.

1. Determine the total volume of ELAPRASE to be administered and the number of vials needed based on the patient's weight and the recommended dose of 0.5 mg/kg.

   Patient's weight (kg) × 0.5 mg/kg of ELAPRASE ÷ 2 mg/mL /vial = Total # mL of ELAPRASE

   Total # mL of ELAPRASE ÷ 3 mL/vial = Total # of vials

   If the number of vials calculated indicates that a partial vial is required, round up to determine the number of whole vials needed from which to withdraw the calculated volume of ELAPRASE to be administered.

2. Perform a visual inspection of each vial. ELAPRASE is a clear to slightly opalescent, colourless solution. Do not use if the solution in the vials is discoloured or particulate matter is present. ELAPRASE should not be shaken.
3. Withdraw the calculated volume of ELAPRASE from the appropriate number of vials.
4. Dilute the total calculated volume of ELAPRASE in 100 mL of 0.9% Sodium Chloride for Injection. Once diluted into normal saline, the solution in the infusion bag should be mixed gently, but not shaken. To reduce microbial hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2°- 8°C for no more than 24 hours.
5. ELAPRASE is supplied in single-use vials. Remaining ELAPRASE left in a vial after withdrawing the patient's calculated dose should be disposed of in accordance with local requirements.

Compatibility:

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

IN-USE STORAGE CONDITIONS

ELAPRASE is for single use in one patient only. This product contains no preservatives. To reduce microbial hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2°- 8°C for no more than 24 hours.

SPONSOR

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