PACKAGE INSERT – Myozyme - Powder for solution for infusion

NAME OF THE MEDICINE

Alglucosidase alfa.

DOSAGE FORM

Powder for concentrate for solution for infusion.

METHOD OF PREPARATION

Preparation:

Each reconstituted vial must be diluted prior to administration in 0.9% sodium chloride for injection.

Use Aseptic Techniques

1. Determine the number of vials to be reconstituted based on the individual patient's weight and the recommended dose of 20 mg/kg.

   Patient weight (kg) x dose (mg/kg) = patient dose (in mg).

   Patient dose (in mg) divided by 50 mg/vial = number of vials to reconstitute. If the number of vials includes a fraction, round up to the next whole number for vials needed to withdraw the calculated volume of MYOZYME required.

   Patient dose (in mg) ÷ 5 mg/mL = total number of mL required of reconstitution MYOZYME solution.

   Example:

   Patient weight (16 kg) x dose (20 mg/kg) = patient dose (320 mg). 320 mg divided by 50 mg/vial = 6.4 vials therefore, 7 vials should be reconstituted.

2. Remove the required number of vials from the refrigerator and allow them to reach room temperature prior to reconstitution (approximately 30 minutes). Reconstitute each vial by slowly injecting 10.3 mL of sterile water for injection to the inside wall of each vial. Each vial will yield 5 mg/mL. The total extractable dose per vial is 50 mg per 10 mL. Avoid forceful impact of the water for injection on the powder and avoid foaming. This is done by slow drop-wise addition of the water for injection down the inside of the vial and not directly onto the lyophilised cake. Tilt and roll each vial gently. Do not invert, swirl, or shake.
3. The reconstituted MYOZYME solution should be protected from light.
4. Perform an immediate visual inspection on the reconstituted vials for particulate matter and discolouration. If upon immediate inspection opaque particles are observed or if the solution is discoloured do not use. The reconstituted solution may occasionally contain some alglucosidase alfa rch particles in the form of thin white strands or translucent fibres subsequent to the initial inspection. This may also happen following dilution for infusion. These particles have been shown to contain alglucosidase alfa rch and may appear after the initial reconstitution step and increase over time. Studies have shown that these particles are removed via in-line filtration without having a detectable effect on the purity or strength.
5. Withdraw the calculated volume of MYOZYME from the appropriate number of vials.
6. MYOZYME should be diluted in 0.9% sodium chloride for injection immediately after reconstitution to a final concentration of 0.5 to 4 mg/mL.
7. Slowly withdraw the reconstituted solution from each vial. Avoid foaming in the syringe.
8. Remove airspace from the infusion bag to minimise particle formation due to the sensitivity of MYOZYME to air - liquid interfaces.
9. Add the reconstituted MYOZYME solution slowly and directly into the sodium chloride solution. Do not add directly into airspace that may remain within the infusion bag. Avoid foaming in the infusion bag.
10. Gently invert or massage the infusion bag to mix. Do not shake. To reduce microbial hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2°C - 8°C for no more than 24 hours. Protect from light.

The diluted solution should be filtered through a 0.2 µm, low protein - binding, in - line filter during administration to remove any visible particles.

Compatibility:

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

IN-USE STORAGE CONDITIONS

The reconstituted MYOZYME solution should be protected from light.

To reduce microbial hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2°C - 8°C for no more than 24 hours. Protect from light.

After reconstitution: MYOZYME IS FOR SINGLE USE IN ONE PATIENT ONLY. Remaining MYOZYME left in a vial after withdrawing the patient's calculated dose should be disposed of in accordance with local requirements.

SPONSOR

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VERSION/DATE OF REVISION

Version 2.0 – 29 May 2026