PACKAGE INSERT – Xenpozyme – Powder for injection

NAME OF THE MEDICINE

Olipudase alfa

DOSAGE FORM

Powder for injection

METHOD OF PREPARATION

Preparation:

Xenpozyme must be reconstituted with sterile water for injections, diluted with sodium chloride 9 mg/mL (0.9%) solution for injection and then administered by intravenous infusion.

The reconstitution and dilution steps must be completed under aseptic technique. Avoid foaming during reconstitution and dilution steps.

a) Determine the number of vials to be reconstituted based on the individual patient's weight (BMI < 30) or an optimal body weight (BMI ≥ 30) and the prescribed dose:

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

   Patient dose (mg) / 20 mg/vial = number of vials to reconstitute

   If the number of vials includes a fraction, round up to the next whole number.

b) Remove the required number of vials from the refrigerator and set aside for approximately 20 to 30 minutes to allow them to reach room temperature.

c) 20 mg vial: Reconstitute each vial by injecting 5.1 mL of sterile water for injections into the vial using a slow drop-wise addition technique to the inside wall of the vial.

   4 mg vial: Reconstitute each vial by injecting 1.1 mL of sterile water for injections into the vial using a slow drop-wise addition technique to the inside wall of the vial.

d) Tilt and roll each vial gently. Each vial will yield a 4 mg/mL clear, colourless solution.

e) Visually inspect the reconstituted solution in the vials for particulate matter and discolouration. Xenpozyme solution should be clear and colourless. Any vials exhibiting opaque particles or discolouration should not be used.

f) Withdraw the volume of reconstituted solution, corresponding to the prescribed dose, from the appropriate number of vials and dilute with sodium chloride 9 mg/mL (0.9%) solution for injection, in a syringe or infusion bag depending on the volume of infusion (see Table 1 for the recommended total infusion volume based on patients age and/or weight)

Table 1 - Recommended infusion volumes

	Body weight ≥ 3 kg to < 10 kg	**Body weight ≥ 10 kg to < 20 kg**	**Body weight ≥ 20 kg (paediatric patients < 18 years)**	**Adult patients (≥ 18 years)**
Dose (mg/kg)	Total infusion volume (mL)	Total infusion volume (mL)	Total infusion volume (mL)	Total infusion volume (mL)
0.03	Variable volume will vary based on body weight	Variable volume will vary based on body weight	5	N/A
0.1	Variable volume will vary based on body weight	5	10	20
0.3	5	10	20	100
0.6	10	20	50	100
1	20	50	100	100
2	50	75	200	100

3	50	100	250	100

- For variable final volumes of infusion based on body weight in paediatric patients (see Table 1):
    - Prepare an infusion solution at 0.1 mg/mL by adding 0.25 mL (1 mg) of the reconstituted solution prepared in step c and 9.75 mL of 0.9% sodium chloride for injection into an empty 10 mL syringe
    - Calculate the volume (mL) required to obtain the patient dose (mg)
    - Example: 0.3 mg / 0.1 mg/mL = 3 mL

Dilution instructions for 5 mL ≤ total volume ≤ 20 mL using a syringe:

- Inject the required volume of the reconstituted solution slowly to the inside wall of the empty syringe
- Add slowly the sufficient quantity of sodium chloride 9 mg/mL (0.9%) solution for injection to obtain the required total infusion volume (avoid foaming with the syringe)

Dilution instructions for a total volume ≥ 50 mL using an infusion bag:

- Empty infusion bag:
    - Inject slowly the required volume of the reconstituted solution from step c) in the appropriate size sterile infusion bag
    - Add slowly the sufficient quantity of sodium chloride 9 mg/mL (0.9%) solution for injection to obtain the required total infusion volume (avoid foaming within the bag)
- Pre-filled infusion bag:
    - Withdraw from the infusion bag pre-filled with sodium chloride 9 mg/mL (0.9%) solution for injection the volume of normal saline to obtain a final volume as specified in Table 1
    - Add slowly the solution withdrawn in step c) into the infusion bag (avoid foaming within the bag)

g) Gently invert the syringe or the infusion bag to mix. Do not shake. Because this is a protein solution, slight flocculation (described as thin translucent fibres) occurs occasionally after dilution.

h) The diluted solution must be filtered through an in-line low protein-binding 0.2 µm filter during administration.

i) After the infusion is complete, the infusion line should be flushed with sodium chloride 9 mg/mL (0.9%) solution for injection using the same infusion rate as the one used for the last part of the infusion.

Xenpozyme is for intravenous use only. Infusions should be administered in a stepwise manner preferably using an infusion pump.

At the end of infusion (once the syringe or infusion bag is empty), the infusion line should be flushed with sodium chloride 9 mg/mL (0.9%) solution using the same infusion rate as the one used for the last part of the infusion.

Compatibility:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Xenpozyme is for intravenous use only. Infusions should be administered in a stepwise manner preferably using an infusion pump. Filtering devices should not be used at any time during the preparation of the infusion solution.

IN-USE STORAGE CONDITIONS

From a microbiological point of view, the reconstituted and diluted medicinal product should be used immediately.

If not used immediately, chemical, physical and microbiological in use stability has been demonstrated for up to 24 hours at 2°C to 8°C, followed by 12 hours (including infusion time) at room temperature (up to 25°C) for diluted medicinal product. If not used immediately, reconstituted medicinal product has demonstrated stability for up to 24 hours at 2°C to 8°C, or 6 hours at room temperature (up to 25°C).

Xenpozyme is for single use in one patient only. Discard any residue.

SPONSOR

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VERSION/DATE OF REVISION

Version 2.0 – 02 June 2026