

Products: Oncaspar® 750 U/ml solution for injection/infusion and Oncaspar® 750 U/ml powder for solution for injection/infusion

Can we use the weight of pegaspargase or the density to prepare the appropriate dose of the product?

To prepare the administered dose, the only validated method is the one described in the SmPC (as below), as approved by competent authorities. The posology is calculated in Units. One mL of the solution (or the reconstituted solution) contains 750 Units and one vial (5 ml solution or 5 ml solution after reconstitution) contains 3 750 Units of pegaspargase. See more details below or in the SmPc.

Using another method of calculation to determine the administrated volume for the patient, with the density or the weight of the protein can lead to a mis-dosage of the product and therefore will be an off-label use. *Les Laboratoires Servier* do not recommend any changes from the validated method of preparation. Any deviation to the SmPc must be reported to pharmacovigilance.

Therefore, there is no need to get the density of ONCASPAR, nor the weight of the protein to calculate or verify the dosage of an ONCASPAR preparation.

Please find hereafter the relevant information from ONCASPAR EPAR-Product information to calculate the administered volume needed:

ONCASPAR® 750 U/ml powder for solution for injection/infusion

One ml of solution contains 750 Units (U)** of pegaspargase*. One vial of 5 ml solution contains 3,750 Units.

ONCASPAR® 750 U/ml solution for injection/infusion

Each vial contains 3,750 Units (U)** of pegaspargase*. After reconstitution, 1 ml of solution contains 750 U pegaspargase (750 U/ml).

Posology:

- Paediatric patients and adults ≤ 21 years:

The recommended dose in patients with a body surface area (BSA) ≥ 0.6 m² and who are ≤ 21 years of age is **2,500 U** of pegaspargase (equivalent to **3.3 ml Oncaspar**)/m² body surface area every 14 days.

Children with a body surface area < 0.6 m² should receive 82.5 U of pegaspargase (equivalent to 0.1 mL Oncaspar)/kg body weight every 14 days.

- -Adults > 21 years:

Unless otherwise prescribed, the recommended posology in adults aged > 21 years is 2,000 U of pegaspargase (equivalent to 2.67 ml Oncaspar)/m² body surface area every 14 days.

Treatment may be monitored based on the trough serum asparaginase activity measured before the next administration of pegaspargase. If asparaginase activity values fail to reach target levels, a switch to a different asparaginase preparation could be considered.

Reconstitution

- 1) **5.2 ml water for injections** are injected into the vial using a syringe and 21 gauge needle.
- 2) The vial should be gently swirled until the powder is reconstituted.
- 3) After reconstitution, the solution should be clear, colourless and free from visible foreign particles. Do not use if the reconstituted solution is cloudy or if a precipitate has formed. Do not shake.
- 4) The solution should be used within 24 hours after reconstitution, when stored below 25°C.

Administration

- 1) Parenteral medicinal products should be inspected for particulate matter prior to administration, only a clear, colourless solution free from visible foreign particles should be used.
- 2) The medicinal product should be administered intravenously or intramuscularly. The solution should be administered slowly. For intramuscular injection, the volume should not exceed 2 ml in children and adolescents and 3 ml in adults. For intravenous administration, the reconstituted solution should be diluted in **100 ml sodium chloride 9 mg/ml (0.9%) solution for injection or 5% glucose solution**. The diluted solution can be given over 1 to 2 hours together with an already-running infusion of either sodium chloride 9 mg/ml (0.9%) solution or 5% glucose. Do not infuse other medicinal products through the same intravenous line during administration of Oncaspar. After dilution, the solution should be used immediately. If immediate use is not possible, the diluted solution can be stored at 2°C-8°C for up to 48 hours.

Reference:

Oncaspar epar product information

https://www.ema.europa.eu/en/documents/product-information/oncaspar-epar-product-information_en.pdf