
Instructions for Use for Healthcare Professionals Handling Soliris

The following information is intended for medical or healthcare professionals only:

1- How is Soliris supplied?

Each vial of Soliris contains 300 mg of active ingredient in 30 ml of product solution.

2- Before Administration

Reconstitution and dilution should be performed in accordance with good practices rules, particularly for the respect of asepsis.

Soliris should be prepared for administration by a qualified healthcare professional using aseptic technique.

- Inspect visually Soliris solution for particulate matter and discolouration.
- Withdraw the required amount of Soliris from the vial(s) using a sterile syringe.
- Transfer the recommended dose to an infusion bag.
- Dilute Soliris to a final concentration of 5 mg/ml (initial concentration divided by 2) by adding the appropriate amount of diluent to the infusion bag. For 300 mg doses, use 30 ml of Soliris (10 mg/ml) and add 30 ml of diluent. For 600 mg doses, use 60 ml of Soliris and add 60 ml of diluent. For 900 mg doses, use 90 ml of Soliris and add 90 ml of diluent. For 1,200 mg doses, use 120 ml of Soliris and add 120 ml of diluent. The final volume of a 5 mg/ml diluted Soliris solution is 60 ml for 300 mg doses, 120 ml for 600 mg doses, 180 ml for 900 mg doses or 240 ml for 1,200 mg doses.
- Diluents are Sodium chloride 9 mg/ml (0.9%) solution for injection, Sodium chloride 4.5 mg/ml (0.45%) solution for injection or 5% dextrose in Water.
- Gently agitate the infusion bag containing the diluted Soliris solution to ensure thorough mixing of the medicinal product and diluent.
- The diluted solution should be allowed to warm to room temperature [18°C – 25°C] prior to administration by exposure to ambient air.
- The diluted solution must not be heated in a microwave or with any heat source other than the prevailing room temperature.
- Discard any unused portion left in a vial as the medicinal product contains no preservatives.
- Diluted solution of Soliris may be stored at 2°C – 8°C for up to 24 hours prior to administration.

3- Administration

- Do not administer Soliris as an intravenous push or bolus injection.
- Soliris should only be administered via intravenous infusion.
- The diluted solution of Soliris should be administered by intravenous infusion over 25 to 45 minutes (35 minutes ± 10 minutes) in adults and 1-4 hours in paediatric patients under 18 years of age via gravity feed, a syringe-type pump, or an infusion pump. It is not necessary to protect the diluted solution of Soliris from light during administration to the patient.

The patient should be monitored for one hour following infusion. If an adverse event occurs during the administration of Soliris, the infusion may be slowed or stopped at the discretion of the physician. If the infusion is slowed, the total infusion time may not exceed two hours in adults and four hours in paediatric patients under 18 years of age.

4- Special Handling and Storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light. Soliris vials in the original package may be removed from refrigerated storage **for only one single period of up to 3 days**. At the end of this period the product can be put back in the refrigerator.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.