

Instructions for administration

Entyvio should be stored in a refrigerator (2°C-8°C). Keep the vial in the outer carton in order to protect from light.

When reconstituted, Entyvio should be at room temperature (20°C -25°C).

1. Use aseptic technique when preparing Entyvio solution for intravenous infusion. Remove flip-off cap from the vial and wipe with alcohol swab. Reconstitute vedolizumab with 4.8 ml of sterile water for injection, using a syringe with a 21-25 gauge needle.
2. Insert the needle into the vial through the centre of the stopper and direct the stream of liquid to the wall of the vial to avoid excessive foaming.
3. Gently swirl the vial for at least 15 seconds. Do not vigorously shake or invert.
4. Let the vial sit for up to 20 minutes to allow for reconstitution and for any foam to settle; the vial can be swirled and inspected for dissolution during this time. If not fully dissolved after 20 minutes, allow another 10 minutes for dissolution.
5. Inspect the reconstituted solution visually for particulate matter and discoloration prior to administration. Solution should be clear or opalescent, colourless to light yellow and free of visible particulates. Reconstituted solution with uncharacteristic colour or containing particulates must not be administered.
6. Prior to withdrawing reconstituted solution from vial, gently invert vial 3 times.
7. Withdraw 5 ml (300 mg) of reconstituted Entyvio using a syringe with a 21-25 gauge needle.
8. Add the 5 ml (300 mg) of reconstituted Entyvio to 250 ml of sterile 0.9% sodium chloride solution, and gently mix the infusion bag (5 ml of 0.9% sodium chloride solution does not have to be withdrawn from the infusion bag prior to adding Entyvio). Do not add other medicinal products to the prepared infusion solution or intravenous infusion set. Administer the infusion solution over 30 minutes (see section 4.2).

Entyvio does not contain preservatives. Once reconstituted, the infusion solution should be used as soon as possible. However, if necessary, the infusion solution may be stored for up to 24 hours: this 24 hour hold may include up to 12 hours at 20°C-25°C; any additional hold time must be at 2°C -8°C. Do not freeze. Do not store any unused portion of the infusion solution for reuse.

Each vial is for single-use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.