

The following information is intended for healthcare professionals only

המידע הבא מיועד לצוות רפואי בלבד

المعلومات التالية معدة للطواقم الطبي فقط

Traceability

In order to improve the traceability of biological medicinal products, the name of the administered product should be clearly recorded.

It is recommended to record the batch number as well.

Incompatibilities

This medicinal product must not be mixed with other injectable medicinal products.

Storage of the product

Unopened vial

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original carton in order to protect from light.

Reconstituted solution

When stored in the original carton, chemical and physical in-use stability of the reconstituted medicinal product has been demonstrated for up to 8 hours at room temperature ($\leq 25^{\circ}\text{C}$) or for up to 24 hours at 2°C – 8°C.

From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2°C – 8°C.

Do not freeze the reconstituted solution.

Dose calculation

The total dose, according to the patient's weight (kg) can be calculated as follow:

Total dose (mg) = Dose level (mg/kg) x patient's weight (kg) every three weeks.

Reconstitution instructions

Reblozyl is supplied as a lyophilised powder to be reconstituted with water for injections (WFI). A syringe with appropriate graduations must be used for reconstitution to ensure accurate dosage. See Table 1.

Table 1. Reblozyl reconstitution table

Strength	Amount of WFI required for reconstitution	Post-reconstitution concentration (nominal value)
25 mg vial	0.68 mL	50 mg/mL (0.5 mL)
75 mg vial	1.6 mL	50 mg/mL (1.5 mL)

1. Remove the coloured cap from the vial and wipe the top with an alcohol wipe.
2. Add WFI into the vial by means of a syringe with appropriate graduations with a needle directing the flow onto the lyophilised powder. Allow to stand for one minute.
3. Discard the needle and syringe used for reconstitution. Do not use them for subcutaneous injection.
4. Gently swirl the vial in a circular motion for 30 seconds. Stop swirling and let the vial sit in an upright position for 30 seconds.
5. Inspect the vial for undissolved powder in the solution. If undissolved powder is observed, repeat step 4 until the powder is completely dissolved.
6. Invert the vial and gently swirl in an inverted position for 30 seconds. Bring the vial back to the upright position and let it sit for 30 seconds.
7. Repeat step 6 seven more times to ensure complete reconstitution of material on the sides of the vial.
8. Visually inspect the reconstituted solution prior to administration. When properly mixed, Reblozyl reconstituted solution is a colourless to slightly yellow, clear to slightly opalescent solution which is free of visible foreign particulate matter. Do not use if undissolved product or foreign particulate matter is observed.
9. If the reconstituted solution is not used immediately, see *Storage of the product* section above.

Method of administration

If the Reblozyl reconstituted solution has been refrigerated, remove from the refrigerator 15-30 minutes prior to injection to allow it to reach room temperature. This will allow for a more comfortable injection.

The recommended maximum volume of medicinal product per injection site is 1.2 mL. If more than 1.2 mL is required, the total volume of Reblozyl should be divided into separate similar volume injections and administered across separate sites using the same anatomical location but on opposite sides of the body. Reconstitute the appropriate number of Reblozyl vials to achieve the desired dose.

Inject Reblozyl subcutaneously into the upper arm, thigh or abdomen.

If multiple injections are required, use a new syringe and needle for each subcutaneous injection. Discard any unused portion. Do not administer more than one dose from a vial.

Disposal

Dispose of any unused medicinal product or waste material in accordance with local requirements.