Reblozyl®

(luspatercept-aamt)
for injection 25mg • 75mg

REBLOZYL is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

REBLOZYL is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

RECONSTITUTING REBLOZYL

For anemia in adults with β-thalassemia requiring regular RBC transfusions

REBLOZYL should be reconstituted and administered by a healthcare professional[1]

Reconstitution volumes			
Vial size	**Amount of Sterile Water for Injection, USP required for reconstitution**	**Final concentration**	**Deliverable volume**
25 mg vial	0.68 mL	25 mg/0.5 mL	0.5 mL
75 mg vial	1.6 mL	75 mg/1.5 mL (50 mg/mL)	1.5 mL

Important considerations for REBLOZYL reconstitution[1]

- Reconstitute REBLOZYL with Sterile Water for Injection, USP only
- Reconstitute the number of REBLOZYL vials to achieve the appropriate dose based on the patient's weight
- Use a syringe with suitable graduations for reconstitution to ensure accurate dosage

REBLOZYL is available in
2 strengths as single-dose vials for reconstitution[1]

75 mg 25 mg

Please see full Prescribing Information for REBLOZYL.

Adhere to the following steps to properly reconstitute REBLOZYL for subcutaneous (SC) injection[1]

1. Add Sterile Water for Injection, USP.
Reconstitute with Sterile Water for Injection, USP using volumes described in the reconstitution volumes table on the previous page with the stream directed onto the lyophilized powder. Allow to stand for 1 minute.

2. Discard the needle and syringe used for reconstitution.
The needle and syringe used for reconstitution should not be used for SC injections.

3. Mix and wait.
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.

4. Inspect.
Inspect the vial for undissolved particles in the solution. If undissolved powder is observed, repeat step 3 until the powder is completely dissolved.

5. Mix and wait.
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.

6. Repeat.
Repeat step 5 seven more times to ensure complete reconstitution of material on the sides of the vial.

7. Inspect.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. REBLOZYL is a colorless to slightly yellow, clear to slightly opalescent solution, which is free of foreign particulate matter. Do not use if undissolved product or foreign particulate matter is observed.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism
Thromboembolic events (TEE) were reported in 8/223 (3.6%) REBLOZYL-treated patients. TEEs included deep vein thrombosis, pulmonary embolus, portal vein thrombosis, and ischemic stroke. Patients with known risk factors for thromboembolism (splenectomy or concomitant use of hormone replacement therapy) may be at further increased risk of thromboembolic conditions. Consider thromboprophylaxis in patients at increased risk of TEE. Monitor patients for signs and symptoms of thromboembolic events and institute treatment promptly.

Hypertension
Hypertension was reported in 10.7% (61/571) of REBLOZYL-treated patients. Across clinical studies, the incidence of Grade 3 to 4 hypertension ranged from 1.8% to 8.6%. In patients with beta thalassemia with normal baseline blood pressure, 13 (6.2%) patients developed systolic blood pressure (SBP) >130 mm Hg and 33 (16.6%) patients developed diastolic blood pressure (DBP) >80 mm Hg. Monitor blood pressure prior to each administration. Manage new or exacerbations of preexisting hypertension using anti-hypertensive agents.

Embryo-Fetal Toxicity
REBLOZYL may cause fetal harm when administered to a pregnant woman. REBLOZYL caused increased post-implantation loss, decreased litter size, and an increased incidence of skeletal variations in pregnant rat and rabbit studies. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 3 months after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurring in 1% of patients included cerebrovascular accident and deep vein thrombosis. A fatal adverse reaction occurred in 1 patient treated with REBLOZYL who died due to an unconfirmed case of acute myeloid leukemia (AML).

Most common adverse reactions (at least 10% for REBLOZYL and 1% more than placebo) were headache (26% vs 24%), bone pain (20% vs 8%), arthralgia (19% vs 12%), fatigue (14% vs 13%), cough (14% vs 11%), abdominal pain (14% vs 12%), diarrhea (12% vs 10%) and dizziness (11% vs 5%).

LACTATION

It is not known whether REBLOZYL is excreted into human milk or absorbed systemically after ingestion by a nursing infant. REBLOZYL was detected in milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because many drugs are excreted in human milk, and because of the unknown effects of REBLOZYL in infants, a decision should be made whether to discontinue nursing or to discontinue treatment. Because of the potential for serious adverse reactions in the breastfed child, breastfeeding is not recommended during treatment and for 3 months after the last dose.

Please see full Prescribing Information for REBLOZYL.

Reference: 1. REBLOZYL [Prescribing Information]. Summit, NJ: Celgene Corporation; 2019.

Learn more about the reconstitution process for REBLOZYL by visiting REBLOZYLpro.com

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