

REBLOZYL® (luspatercept-aamt)

Patient Information
REBLOZYL® (REB-low-zil)
(luspatercept-aamt)
for injection, for subcutaneous use

What is REBLOZYL?

REBLOZYL is a prescription medicine used to treat anemia (low red blood cells) in adults with:

- beta thalassemia who need regular red blood cell (RBC) transfusions.
- myelodysplastic syndromes who may need regular RBC transfusions and have never received an erythropoiesis stimulating agent (ESA).
- myelodysplastic syndromes with ring sideroblasts (MDS-RS) or myelodysplastic/myeloproliferative neoplasms with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) who need 2 or more RBC units over 8 weeks and have not responded well to an ESA.

REBLOZYL is not for use as a substitute for RBC transfusions in people who need immediate treatment for anemia. It is not known if REBLOZYL is safe and effective in children.

Before receiving REBLOZYL, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had blood clots
- take hormone replacement therapy or birth control pills (oral contraceptives)
- have had your spleen removed (splenectomy)
- smoke
- have or have had high blood pressure (hypertension)
- have a history of extramedullary hematopoietic (EMH) masses
- have or have had enlarged spleen or liver
- are pregnant or plan to become pregnant. REBLOZYL may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with REBLOZYL.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with REBLOZYL.
- You should use effective birth control (contraception) during treatment with REBLOZYL and for at least 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if REBLOZYL passes into your breast milk.
 - Do not breastfeed during treatment with REBLOZYL and for 3 months after the last dose. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive REBLOZYL?

- Your healthcare provider will prescribe REBLOZYL in a dose that is right for you. Depending on how you respond to REBLOZYL, your healthcare provider may adjust your dose or stop treatment.
- REBLOZYL is given as an injection under your skin (subcutaneous) in the upper arm, thigh, or stomach (abdomen) by your healthcare provider.
- Your healthcare provider will do regular blood tests to check your hemoglobin to monitor if your anemia is getting better before each injection and during your treatment with REBLOZYL.

If your scheduled REBLOZYL dose is delayed or missed, your healthcare provider will give your dose of REBLOZYL as soon as possible and continue your treatment as prescribed with at least 3 weeks between doses.

What are the possible side effects of REBLOZYL?

REBLOZYL may cause serious side effects, including:

- **Blood clots.** Blood clots in the arteries, veins, brain, and lungs have happened in people with beta thalassemia during treatment with REBLOZYL. The risk of blood clots may be higher in people who have had their spleen removed or who take hormone replacement therapy or birth control (oral contraceptives). Call your healthcare provider or get medical help right away if you get any of these symptoms:
 - chest pain
 - trouble breathing or shortness of breath
 - pain in your leg, with or without swelling
 - a cold or pale arm or leg

REBLOZYL® (luspatercept-aamt)

- sudden numbness or weakness that are both short-term or continue to happen over a long period of time, especially on one side of the body
- severe headache or confusion
- sudden problems with vision, speech, or balance (such as trouble speaking, difficulty walking, or dizziness)
- **High blood pressure.** REBLOZYL may cause an increase in your blood pressure. Your healthcare provider will check your blood pressure before you receive your REBLOZYL dose. Your healthcare provider may prescribe you medicine to treat high blood pressure or increase the dose of medicine you already take to treat high blood pressure if you develop high blood pressure during treatment with REBLOZYL.
- **Extramedullary Hematopoietic (EMH) Masses.** EMH masses have happened in people with beta thalassemia during treatment with REBLOZYL. You may have a higher risk for developing EMH masses if you have a history of EMH masses, have had your spleen removed, have or have had an enlarged spleen or liver, or have low hemoglobin levels. Your healthcare provider will monitor you before you start and during treatment with REBLOZYL. Call your healthcare provider or get medical help right away if you get any of these symptoms:
 - severe pain in the back
 - numbness, weakness, or loss of voluntary movement in feet, legs, hands, or arms
 - loss of bowel and bladder control

The most common side effects of REBLOZYL include:

- tiredness
- headache
- back, joint, muscle, or bone pain
- joint pain
- dizziness
- nausea
- diarrhea
- cough
- stomach (abdominal) pain
- trouble breathing
- swelling of your hands, legs, or feet
- high blood pressure
- allergic reactions

REBLOZYL may cause fertility problems in females. This could affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of REBLOZYL.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of REBLOZYL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider or pharmacist for information about REBLOZYL that is written for health professionals.

What are the ingredients in REBLOZYL?

Active ingredient: luspatercept-aamt

Inactive ingredients: citric acid monohydrate, polysorbate 80, sucrose, and tri-sodium citrate dihydrate.

For more information, go to www.REBLOZYL.com or call 1-888-423-5436.

Manufactured by: Celgene Corporation, a Bristol-Myers Squibb Company, 86 Morris Avenue, Summit, NJ 07901

REBLOZYL® is a registered trademark of Celgene Corporation, a Bristol-Myers Squibb Company.

REBPPI V5 8/2023

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: August 2023

2007-US-2300420 08/23