FDA APPROVED FOR ANEMIA

IN MDS

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

FOR PATIENTS WITH RING SIDEROBLASTS WHO ARE FAILING AN ESA AND REQUIRE ≥2 RBC UNITS/8 WEEKS[1]

TAKE THE STEPS TO APPROPRIATELY IDENTIFY YOUR PATIENTS WITH MDS-RS

☐ Check ring sideroblasts and *SF3B1*

- Ring sideroblasts are found in **23%–33% of patients** with MDS and are associated with anemia[2,3]
- MDS-RS classification requires a count of **≥15% ring sideroblasts or ≥5% ring sideroblasts with an *SF3B1* mutation** and could identify patients with MDS-RS who may be eligible for REBLOZYL therapy[4]
- **80% of patients** with MDS-RS also have an *SF3B1* mutation[5]

☐ Communicate and discuss with your pathologist

- Since there is currently a **degree of variability** in how pathologists describe the presence of ring sideroblasts in pathology reports, ask for quantitative reporting[4,6]
- REBLOZYL is approved **specifically for MDS-RS** patients, increasing the importance of quantitative RS reporting[1,4]

☐ Confirm appropriate patient type

- Adult patients who require 2 or more RBC units/8 weeks and have very low- to intermediate-risk MDS-RS or MDS/MPN-RS-T[1]
- Failing an ESA, which can be determined as early as 6–8 weeks of no response[7]

☐ Choose REBLOZYL

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommends luspatercept-aamt (REBLOZYL) as a treatment option after 6–8 weeks of no response to ESAs +/- G-CSF[7]*

*For symptomatic anemia in very low- to intermediate-risk MDS with ring sideroblasts (≥15% or ≥5% with an *SF3B1* mutation) and with serum EPO ≤500 mU/mL and no del(5q) ± other cytogenetic abnormalities.

del(5q), deletion 5q; ESA, erythropoiesis-stimulating agent; G-CSF, granulocyte-colony stimulating factor; MDS-RS, myelodysplastic syndromes with ring sideroblasts; NCCN=National Comprehensive Cancer Network® (NCCN®); RBC, red blood cell.

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

IMPORTANT SAFETY INFORMATION

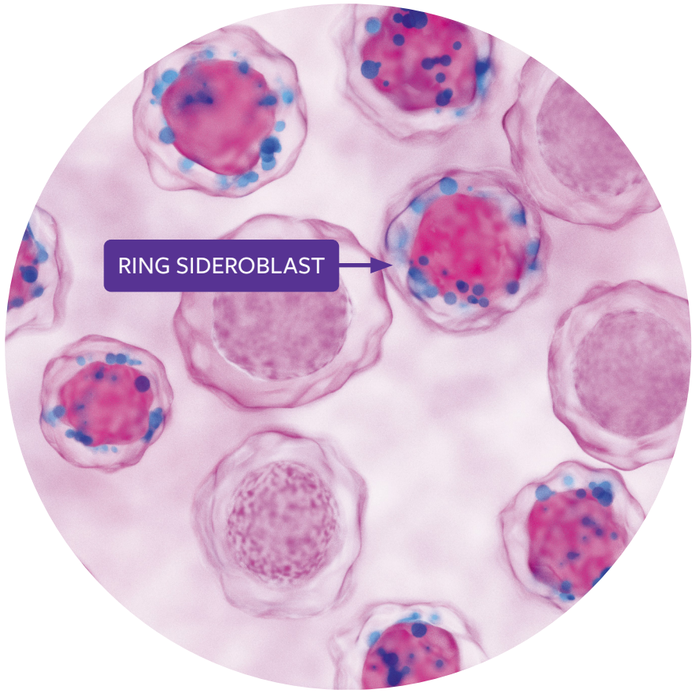
WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

In adult patients with beta thalassemia, 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.

Please see Important Safety Information on next page and full Prescribing Information.

RING SIDEROBLASTS AS IDENTIFIED BY IRON STAINING



INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

REBLOZYL is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

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

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombosis/Thromboembolism

In adult patients with beta thalassemia, 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 adult patients with MDS with normal baseline blood pressure, 26 (29.9%) patients developed SBP ≥130 mm Hg and 23 (16.4%) patients developed 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 final dose.

ADVERSE REACTIONS

Grade ≥3 (≥2%) adverse reactions included fatigue, hypertension, syncope and musculoskeletal pain. A fatal adverse reaction occurred in 5 (2.1%) patients.

The most common (≥10%) adverse reactions included fatigue, musculoskeletal pain, dizziness, diarrhea, nausea, hypersensitivity reactions, hypertension, headache, upper respiratory tract infection, bronchitis, and urinary tract infection.

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 accompanying full Prescribing Information.

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

FDA APPROVED FOR ANEMIA

IN MDS

Reblozyl®

(luspatercept-aamt)

for injection 25mg • 75mg

When your patients with MDS-RS fail an ESA, where do you go then?

CHOOSE REBLOZYL today for your patients with MDS-RS who are failing an ESA and require ≥2 RBC units/8 weeks[1]

To learn more about the importance of testing to diagnose MDS-RS, visit diagnosingmds-rs.com

REBLOZYL is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

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

Please see accompanying full Prescribing Information.

References: 1. REBLOZYL [Prescribing Information]. Summit, NJ: Celgene Corporation; 2020. **2.** Papaemmanuil E, Gerstung M, Malcovati L, et al. Clinical and biological implications of driver mutations in myelodysplastic syndromes. *Blood.* 2013;122(22):3616-3627. **3.** Malcovati L, Cazzola M. Recent advances in the understanding of myelodysplastic syndromes with ring sideroblasts. *Br J Haematol.* 2016;174(6):847-858. **4.** Arber DA, Orazi A, Hasserjian R, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood.* 2016;127(20):2391-2405. **5.** Malcovati L, Papaemmanuil E, Bowen DT, et al; Chronic Myeloid Disorders Working Group of the International Cancer Genome Consortium and of the Associazione Italiana per la Ricerca sul Cancro Gruppo Italiano Malattie Mieloproliferative. Clinical significance of SF3B1 mutations in myelodysplastic syndromes and myelodysplastic/myeloproliferative neoplasms. *Blood.* 2011;118(24):6239-6246. **6.** Sever C, Abbott CL, de Baca ME. Bone marrow synoptic reporting for hematologic neoplasms: guideline from the College of American Pathologists Pathology and Laboratory Quality Center. *Arch Pathol Lab Med.* 2016;140(9):932-949. **7.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V.1.2023. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed November 28, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

2007-US-2200440 12/22

Bristol Myers Squibb™