

PATIENT MEDICATION INFORMATION – USE IN BETA-THALASSEMIA

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrREBLOZYL®

luspatercept for injection

Read this carefully before you start taking **Reblozyl®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Reblozyl®**.

What is Reblozyl® used for?

Reblozyl® is used to treat adults who have low red blood cell counts (anemia) and require red blood cell transfusions due to a blood disorder (β -thalassemia) that affects the production of hemoglobin (a protein in the red blood cells that transports oxygen throughout the body).

How does Reblozyl® work?

Reblozyl® may improve red blood cell production and increase hemoglobin levels, reducing the need for red blood cell transfusions.

What are the ingredients in Reblozyl®?

Medicinal ingredients: luspatercept

Non-medicinal ingredients: Non-medicinal ingredients: citric acid monohydrate, hydrochloric acid, polysorbate 80, sodium hydroxide, sucrose, tri-sodium citrate dihydrate

Reblozyl® comes in the following dosage forms:

Reblozyl® is a powder that will be mixed with sterile water before it is injected under the skin (subcutaneous injection). It comes in vials and is available in two strengths 25 mg and 75 mg.

Do not use Reblozyl® if:

- You are allergic to luspatercept or any of the other ingredients in Reblozyl®.

If you are not sure, talk to your doctor or nurse before you are given Reblozyl®.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Reblozyl®. Talk about any health conditions or problems you may have, including if:

- You are a β -thalassemia patient and have had your spleen removed. You may have a higher risk for a blood clot when given Reblozyl®. Discuss with your doctor other potential risk factors that may increase your risk including hormone replacement therapy or a previous blood clot. Your doctor may use preventive measures or medication to reduce the likelihood of a blood clot formation.
- You are a β -thalassaemia patient with medical history of mass producing blood cells outside the bone marrow (extramedullary haematopoiesis masses, EMH masses), or with low hemoglobin, spleen removed, or enlarged liver/spleen. You may have a high risk of EMH

masses. Your doctor will talk to you about other possible risk factors that may increase your risk - these include:

- compression of the spinal cord.
- You have or previously had high blood pressure, since Reblozyl® may increase it. Your blood pressure will be monitored before Reblozyl® administration and throughout treatment.

Other warnings you should know about:

Pregnancy:

- Do not use this medicine during pregnancy. Reblozyl® may cause harm to your unborn baby.
- Your healthcare professional may arrange a pregnancy test before treatment.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before taking this medicine.

Breast-feeding:

- Do not breast-feed when using this medicine and for at least 3 months after your last dose. It is not known if Reblozyl® passes into the mother's milk.

Contraception:

- Women of childbearing potential should use an effective method of contraception during treatment with Reblozyl® and for at least 3 months after their last dose.
- You should not become pregnant while you are taking this medicine. Reblozyl® may cause harm to your unborn baby.

Fertility:

- If you are a woman, this medicine may cause fertility problems, which may affect your ability to have a baby. Talk to your healthcare profession for advice before taking Reblozyl®.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How you will be treated with Reblozyl®

Reblozyl® will be given by injections under your skin. The injections will be given to you by a doctor, nurse or other healthcare professional.

You will have a blood test to measure your hemoglobin level before you receive Reblozyl®. If your hemoglobin level is too high, you may not receive Reblozyl® at your visit. Your blood pressure will also be monitored before each administration of this medicine and throughout treatment.

Usual dose:

The dose you are given will be based on your body weight in kilograms.

- The recommended starting dose is 1.0 mg/kg of body weight once every three weeks.
- The highest recommended dose is 1.25 mg/kg of body weight once every three weeks.

- Your doctor will check your progress and may change your dose if needed.

Overdose:

If you think you, or a person you are caring for, have taken too much Reblozyl®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

In case of a missed or delayed injection of Reblozyl®, you will receive a Reblozyl® injection as soon as possible and your dose will continue as prescribed with at least 3 weeks between doses.

What are possible side effects from using Reblozyl®?

These are not all the possible side effects you may feel when taking Reblozyl®. If you experience any side effects not listed here, contact your healthcare professional.

Very common side effects (may affect more than 1 in 10 people):

- dizziness, headache
- bone pain and/or joint pain
- fatigue (tired or feeling weak)
- cough
- abdominal pain
- diarrhea

Common side effects (may affect up to 1 in 10 people):

- flu-like symptoms
- nausea
- upper respiratory tract infections
- increase blood pressure
- high level of uric acid in the blood (hyperuricaemia)
- injection site reactions: redness, burning and pain at the site of the injection

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Anemia (decrease in red blood cells): tiredness, fatigue		√	
Cellulitis (skin infection): red, swollen, hot, tender area of the skin.			√
Cholangitis (inflammation of the bile duct system): abdominal pain, fever, chills, yellowing of skin/eyes, nausea, vomiting, clay-coloured stools, dark urine, tiredness			√
Deep vein thrombosis (blood clots that form in your blood vessels): arm or leg pain with swelling			√
Extramedullary Haematopoiesis (EMH) Masses (mass producing blood cells outside the bone marrow): severe pain in the back that does not go away, numbness or weakness or loss of voluntary movement in legs, hands or arms, loss of bowel and bladder control			√
Fever		√	
Septic shock (overwhelming infection): fever, chills, very low body temperature, decreased urine, rapid heart beat, rapid breathing, nausea, vomiting, diarrhea			√
Stroke: difficulty moving limbs, walking or speaking			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Reblozyl® will be stored in a refrigerator at 2-8°C. Do not freeze.

Keep out of reach and sight of children.

If you want more information about Reblozyl®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://bms.com/ca/en>, or by calling 1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada, St-Laurent, QC, Canada H4S 0A4.

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PATIENT MEDICATION INFORMATION – USE IN MYELODYSPLASTIC SYNDROMES

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What is Reblozyl® used for?

Reblozyl® is used in adults who have low red blood cell counts (anemia) and require red blood cell transfusions due to a blood and bone marrow disorder called myelodysplastic syndromes.

How does Reblozyl® work?

Reblozyl® may improve red blood cell production and increases hemoglobin levels, reducing the number of red blood cell transfusions.

What are the ingredients in Reblozyl®?

Medicinal ingredients: luspatercept

Non-medicinal ingredients: citric acid monohydrate, hydrochloric acid, polysorbate 80, sodium hydroxide, sucrose, tri-sodium citrate dihydrate

Reblozyl® comes in the following dosage forms:

Reblozyl® is a powder that will be mixed with sterile water before it is injected under the skin (subcutaneous injection). It comes in vials and is available in two strengths 25 mg and 75 mg.

Do not use Reblozyl® if:

- You are allergic to luspatercept or any of the other ingredients in Reblozyl®.

If you are not sure, talk to your doctor or nurse before you are given Reblozyl®.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Reblozyl®. Talk about any health conditions or problems you may have, including if:

- You have or previously had high blood pressure, since Reblozyl® may increase it. Your blood pressure will be monitored before Reblozyl® administration and throughout treatment.

Other warnings you should know about:

Pregnancy:

- Do not use this medicine during pregnancy. Reblozyl® may cause harm to your unborn baby.
- Your healthcare professional may arrange a pregnancy test before treatment.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before taking this medicine.

Breast-feeding:

- Do not breast-feed when using this medicine and for at least 3 months after your last dose. It is not known if Reblozyl® passes into the mother's milk.

Contraception:

- Women of childbearing potential should use an effective method of contraception during treatment with Reblozyl® and for at least 3 months after their last dose.
- You should not become pregnant while you are taking this medicine. Reblozyl® may cause harm to your unborn baby.

Fertility:

- If you are a woman, this medicine may cause fertility problems, which may affect your ability to have a baby. Talk to your healthcare profession for advice before taking Reblozyl®.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How you will be treated with Reblozyl®

Reblozyl® will be given by injections under your skin. The injections will be given to you by a doctor, nurse or other healthcare professional.

You will have a blood test to measure your hemoglobin level before you receive Reblozyl®. If your hemoglobin level is too high, you may not receive Reblozyl® at your visit. Your blood pressure will also be monitored before each administration of this medicine and throughout treatment.

Usual dose:

The dose you are given will be based on your body weight in kilograms.

- The recommended starting dose is 1.0 mg/kg of body weight once every three weeks.
- The highest recommended dose is 1.75 mg/kg of body weight once every three weeks.
- Your doctor will check your progress and may change your dose if needed.

Overdose:

If you think you, or a person you are caring for, have taken too much Reblozyl®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

In case of a missed or delayed injection of Reblozyl®, you will receive a Reblozyl® injection as soon as possible and your dose will continue as prescribed with at least 3 weeks between doses.

What are possible side effects from using Reblozyl®?

These are not all the possible side effects you may have when taking Reblozyl®. If you experience any side effects not listed here, tell your healthcare professional.

Very common side effects (may affect more than 1 in 10 people):

- fatigue (tired or feeling weak, low energy)
- nausea, diarrhea or constipation
- dizziness, headache
- back pain
- cough
- difficulty in breathing or shortness of breath
- infection of the bladder (urinary tract infection)

Common side effects (may affect up to 1 in 10 people):

- muscle pain
- flu-like symptoms
- upper respiratory tract infections
- decreased appetite
- increased blood sugar
- injection site reactions: redness, burning and pain at the site of the injection

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Peripheral Edema: swelling of the legs or feet			√
COMMON			
Anemia (decrease in red blood cells): tiredness, fatigue		√	
Basal Cell Carcinoma (certain types of skin cancer): changes in the appearance of your skin or growths on your skin			√
Heart Problems including: Cardiac Failure: shortness of breath, swelling of legs, ankles and feet, rapid heartbeat, cough/wheeze with white/pink phlegm; Angina: chest pain/discomfort; AV block: chest pain, dizziness/fainting,			√

fatigue, shortness of breath, feeling that heart skips a beat			
Kidney failure: lack of urine, shortness of breath, confusion, swelling of legs, ankles, feet; drowsiness/fatigue, nausea			✓
Pneumonia: fever, chills, fatigue, cough, shortness of breath, coughing up thick yellow or green mucous, fast heartbeat		✓	
Progression of MDS to acute myeloid leukemia (AML): fever, bone pain, fatigue, shortness of breath, unusual bleeding, easy bruising.			✓
Sepsis (overwhelming infection): fever, chills, very low body temperature, decreased urine, rapid heart beat, rapid breathing, nausea, vomiting, diarrhea			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
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- Find the full product monograph that is prepared for healthcare professionals and includes this

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(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://bms.com/ca/en>, or by calling 1-866-463-6267.

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