

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

MOZOBIL[®]

Plerixafor injection

This Patient Medication Information is written for the person who will be taking **Mozobil[®]**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have questions about the condition this medication is for or want more information about **Mozobil[®]**, talk to a healthcare professional.

Serious Warnings and Precautions:

Mozobil[®] will be prescribed and managed by a healthcare professional experienced in oncology and/or hematology.

What is Mozobil[®] used for?

Mozobil is used with granulocyte-colony stimulating factor (G-CSF) to help collect blood stem cells for transplantation in:

- adults with non-Hodgkin's lymphoma (a cancer of the white blood cells) and multiple myeloma (a cancer that affects plasma cells in the bone marrow).
- children and adolescents (1 to less than 18 years of age) with lymphoma or solid cancerous tumors, where following G-CSF treatment:
 - blood stem cell count is low on the date planned to collect the blood stem cell , or
 - previous collection did not produce enough stem cells.

How does Mozobil[®] work?

Mozobil contains the medicinal ingredient plerixafor, which blocks a protein on the surface of blood stem cells. This protein "ties" blood stem cells to the bone marrow. Plerixafor improves the release of stem cells from the bone marrow into the blood stream. The stem cells can then be collected by an apheresis machine. The collected stem cells are then frozen and stored until your transplant.

What are the ingredients in Mozobil[®]?

Medicinal ingredients: Plerixafor

Non-medicinal ingredients: Sodium chloride and water for injection. Other ingredients are hydrochloric acid and sodium hydroxide, if required.

Mozobil[®] comes in the following dosage forms:

Solution, 24 mg/1.2 mL (20 mg/mL)

Do not use Mozobil[®] if:

- If you are allergic to plerixafor or any of the other ingredients of Mozobil

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

- have or have had any heart problems. Examples include Wolff-Parkinson-White syndrome or Lown-Ganong-Levine syndrome, or atrioventricular nodal rhythm disorders.
- have kidney problems.
- have high white blood cell counts.
- have low platelet counts.
- have a history of feeling faint or lightheaded on standing or sitting or have fainted following injections.
- have leukemia (a cancer of the blood or bone marrow).

Other warnings you should know about:

Blood tests

Mozobil can cause abnormal blood test results. Your healthcare professional will test your blood during treatment to monitor your blood cell and electrolytes count.

Driving and using machines

Mozobil may cause dizziness and fatigue. Therefore, you should avoid driving if you feel dizzy, tired or unwell.

Female patients

If you are pregnant, or able to get pregnant and/or breast-feed, there are specific risks you must discuss with your healthcare professional.

- Avoid becoming pregnant while taking Mozobil. It may cause harm to your unborn baby. You should use effective methods of birth control while taking Mozobil. Keep using birth control for 1 week after taking your last dose of Mozobil. If you do become pregnant while taking Mozobil, tell your healthcare professional right away.
- It is not known if Mozobil will pass into breast milk. You should not breast-feed if you are using Mozobil. If you are planning to breastfeed, tell your healthcare professional.

Male patients

- Use effective contraception when having sexual intercourse with a woman, who is able to get pregnant. Effective contraception must be used:
 - While you are taking Mozobil, and
 - For one week after your last dose of Mozobil.

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

How to take Mozobil®:

- Mozobil will be given to you by a healthcare professional as an injection under the skin (subcutaneous injection).
- You will receive daily treatments with G-CSF for four days before your first dose of Mozobil.

Usual dose: The dose you will receive will depend on your weight and the condition of your kidneys.

- Adults: Mozobil will be given 10 to 11 hours before stem cells are collected. Treatment will last four consecutive days.
- Children and adolescents: Mozobil will be given 8 to 12 hours before stem cells are collected. Treatment will last three consecutive days.

Overdose:

If you think you, or a person you are caring for, have taken too much Mozobil, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

What are possible side effects from using Mozobil®?

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

- abnormal dreams, nightmares
- feeling tired
- stuffy and runny nose

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Injection site reactions: redness, irritation, swelling, rash, pain, bruising, bleeding, numbness	√		
Fever	√		
Hypoproteinemia (decreased level of protein in blood:): weakness, swelling in the feet, ankles, legs, hands, and / or face	√		
Anemia (decreased red blood cells): fatigue, loss of energy, weakness, shortness of breath	√		
Neutropenia or Leukopenia (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms	√		
Thrombocytopenia (decreased platelets): bruising, bleeding, fatigue and weakness	√		

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Headache	√		
Dizziness: feeling faint, unsteady, likely to experience loss of consciousness	√		
Difficulty in sleeping, anxiety	√		
Flatulence, constipation, indigestion	√		
Stomach problems: pain, swelling or discomfort	√		
Numbness around the mouth, pins and needles and numbness	√		
Sweating, generalized redness of the skin	√		
Joint pains, pains in muscles and bones	√		
UNCOMMON			
Allergic reactions: skin rash, swelling around the eyes, shortness of breath		√	
Sudden drop in blood pressure: Feeling faint, fainting		√	
Heart attack, chest discomfort		√	
Febrile neutropenia (fever with low white blood cell count): fever, signs of low white blood cell count and/or infection		√	
Pancytopenia (decreased red and white blood cells and platelets): bruising, bleeding (gums), nose bleed, weakness, paleness of skin, fatigue, shortness of breath, rapid heart rate, and/or symptoms of infection		√	
RARE			
Severe diarrhea, vomiting, and/or nausea.		√	
UNKNOWN			
Spleen enlargement and/or rupture: pain in the upper left abdomen (belly) or at the tip of your shoulder		√	

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 (canada.ca/drug-device-reporting) 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:

You will not be given Mozobil to store. It will only be stored with the healthcare professional.

If you want more information about Mozobil®:

- 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 www.sanofi.ca or by calling sanofi-aventis Canada Inc., at: 1-800-265-7927.

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