

PART III: CONSUMER INFORMATION**MOZOBIL®
Plerixafor injection**

This leaflet is part III of a three-part "Product Monograph" published when MOZOBIL (plerixafor) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MOZOBIL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

MOZOBIL in combination with granulocyte-colony stimulating factor (G-CSF) is used 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:
 - o Blood stem cell count is low on the predicted date of collection, or
 - o Previous collection has failed to yield enough stem cells

What it does:

MOZOBIL contains the active substance 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 into the blood stream (mobilization). The stem cells can then be collected by an apheresis machine, and subsequently frozen and stored until your transplant.

When it should not be used:

If you or your child are allergic (hypersensitive) to plerixafor or any of the other ingredients of MOZOBIL (see below for a list of important non-medicinal ingredients).

What the medicinal ingredient is:

Plerixafor

What the important nonmedicinal ingredients are:

Sodium chloride (typically less than 6 mg per dose). Other ingredients are hydrochloric acid (concentrated) and sodium hydroxide for pH adjustment and water for injections.

What dosage forms it comes in:

MOZOBIL is supplied as a clear colorless or pale yellow solution for injection in a glass vial with a non-latex rubber stopper. Each vial contains 1.2 mL solution.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions: MOZOBIL will be prescribed and managed by a healthcare professional experienced in oncology and/or hematology.

BEFORE you or your child are given MOZOBIL talk to your doctor or pharmacist if:

- you or your child have or have had any heart problems.
- you or your child have kidney problems.
- you or your child have high white blood cell counts.
- you or your child have low platelet counts.
- you or your child have a history of feeling faint or lightheaded on standing or sitting or have fainted following injections.
- you are pregnant or are planning to become pregnant. Female patients who can get pregnant should use an effective birth control while having treatment with MOZOBIL.
- you are breast feeding.

Your doctor may perform regular blood tests to monitor your blood cell count.

It is not recommended to use MOZOBIL for stem cell mobilization if you have leukemia (a cancer of the blood or bone marrow).

Driving and using machines

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

INTERACTIONS WITH THIS MEDICATION

Before and during treatment with MOZOBIL tell your doctor or pharmacist about your other medicines, including medicines that you bought without a prescription.

PROPER USE OF THIS MEDICATION

You or your child will first receive a treatment with G-CSF once daily for 4 days.

Then MOZOBIL will be given 10 to 11 hours for adults and 8 to 12 hours for children and adolescents before each session of apheresis (a collection of stem cells).

The usual dose of MOZOBIL is 0.24 mg/kg body weight/day given to you as an injection under the skin (subcutaneous injection). For adults who weigh 83 kg or less, your doctor may prescribe a fixed dose of 20 mg of MOZOBIL.

MOZOBIL can be used for up to

- 4 consecutive days in **adults**
- 3 consecutive days in **children and adolescents (1 to less than 18 years of age)**.

OVERDOSE

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MOZOBIL can cause side effects. The following are potential side effects with the use of MOZOBIL:

- Injection site reactions, such as swelling, pain, irritation, bruising
- feeling tired
- stuffy and runny nose
- abnormal dreams, nightmares.

Please tell your doctor immediately if

- shortly after receiving MOZOBIL, you experience rash, swelling around the eyes, shortness of breath or lack of oxygen, feeling lightheaded on standing or sitting, feeling faint or fainting
- you have pain in the upper left abdomen (belly) or at the tip of your shoulder.

Heart attacks

In clinical trials, 0.9% of patients with risk factors for a heart attack suffered heart attacks after being given MOZOBIL and G-CSF. Please inform your doctor immediately if you experience chest discomfort.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very common			
Diarrhea, nausea (feeling sick), injection site redness or irritation	√		
Fever (pyrexia)	√		
Decreased level of protein in blood (hypoproteinemia)	√		
Decreased red blood cells (anemia) – fatigue, loss of energy, weakness, shortness of breath	√		
Decreased white blood cells (neutropenia or leukopenia) – infections, fatigue, fever, aches, pains and flu-like symptoms	√		
Decreased platelets (thrombocytopenia) – bruising, bleeding, fatigue and weakness	√		
Common			
Headache	√		
Dizziness, feeling tired or unwell	√		
Difficulty in sleeping, anxiety	√		
Flatulence, constipation, indigestion, vomiting	√		
Stomach symptoms such as 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			
Systemic reactions such as skin rash, swelling around the eyes, shortness of breath		√	
Feeling faint, sudden drop in pulse and/or blood pressure, fainting		√	
Heart attack, chest discomfort		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and
Fever with low white blood cell count (febrile neutropenia) – fever, signs of low white blood cell count and/or infection		√	
Decreased red and white blood cells and platelets (pancytopenia) –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, stomach pain and/or nausea.		√	
Unknown frequency			
Spleen enlargement and/or rupture: pain in the upper left abdomen (belly) or at the tip of your shoulder		√	

This is not a complete list of side effects. For any unexpected effects while taking MOZOBIL contact your doctor or pharmacist.

HOW TO STORE IT

You will not be given MOZOBIL to store. It will only be administered by a doctor or nurse.

Reporting Suspected 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 care professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: January 9, 2019