Patient & Caregiver Education Booklet
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*Please see additional Important Safety Information on page 8 and full Prescribing Information at http://products.sanofi.us/Mozobil/mozobil.html*
Introduction

This booklet is designed to provide you with information regarding hematopoietic stem cell transplantation (HSCT) to treat your underlying cancer and the use of Mozobil® (plerixafor injection) to help mobilize stem cells. You should always consult your doctor or healthcare professional if you have any questions or concerns regarding your treatment.

Mozobil (MOH-zuh-bil) is approved by the United States Food and Drug Administration (FDA) to be used in combination with another agent (granulocyte-colony stimulating factor [G-CSF, filgrastim]) to mobilize hematopoietic stem cells into the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma. Mozobil is not intended for HSCT mobilization and collection in patients with leukemia.

Hematopoietic stem cell transplantation, referred to as stem cell transplant (SCT) in this booklet, can be a complicated process. This booklet describes what a stem cell transplant is and provides an explanation of each step of the transplant process. In addition, this booklet describes the preparation you will need to undergo before transplant. We hope it will help address many of your questions and provide useful information regarding this process. Throughout the booklet, you will see several words that are highlighted in blue. These words are commonly used by your transplant team and an explanation of what they mean can be found in the glossary (see Glossary tab).

The information in this booklet is not intended to replace the information provided by your doctor or healthcare provider nor is it a substitute for the discussions you should have with your transplant team. This team may include doctors, physician assistants (PAs), nurse practitioners (NPs), registered nurses, pharmacists, social workers, dieticians, and stem cell laboratory staff, among others. It is important to know that the members of a transplant team may vary depending on your transplant center, and you should feel free to consult any member of this team during your treatment.

The calendar section contains a calendar so that you can plot the days you will undergo stem cell mobilization and collection. There is also a calendar for the transplant course. Finally, there is a section with frequently asked questions (FAQs) as well as important resources that can provide assistance and support to SCT patients.

You may find this book a useful reference throughout the course of your transplant.

Please see additional Important Safety Information on page 8 and full Prescribing Information at http://products.sanofi.us/Mozobil/mozobil.html
The Stem Cell Transplant Process

These pictures describe the transplant process in general. Your transplant process will be individualized by your center.

1. **INJECTIONS**
   - Injections of G-CSF and Mozobil® (plerixafor injection) to prepare stem cells to be mobilized

2. **MOBILIZATION**
   - Stem cells are stimulated to move into the bloodstream from the bone marrow space

3. **COLLECTION**
   - Collection of mobilized stem cells from the blood using the apheresis machine

4. **STORAGE**
   - Stem cells collected are stored in infusion bags

5. **FREEZING**
   - Freezing of stem cells until after completion of preparative regimen

6. **CHEMOTHERAPY and/or RADIATION**
   - Preparative regimen as prescribed by your doctor intended to kill any remaining cancer cells, and make a space for your new cells to live

7. **STEM CELL TRANSPLANT**
   - Previously collected stem cells are thawed and infused back into the bloodstream

8. **ENGRAFTMENT and RECOVERY**
   - One aim of autologous stem cell transplant is for infused stem cells to mature into functional blood components such as neutrophils and platelets. The first signs of engraftment and recovery include increasing ANC and platelet counts.

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Please see additional Important Safety Information on page 8 and full Prescribing Information at http://products.sanofi.us/Mozobil/mozobil.html
Chapter 1: The Stem Cell Transplant

What Are Stem Cells?
Hematopoietic stem cells (referred to as stem cells in this booklet) are unique cells that are primarily located in the bone marrow and mature into a number of blood cell types found in your body. The blood cells that are most important when talking about stem cell transplantation include red blood cells (RBCs), white blood cells (WBCs), and platelets.

Where Are Stem Cells Found?
In adults, the bones of the hip and chest contain the greatest amount of bone marrow and stem cells. Stem cells that leave the bone marrow and circulate in the bloodstream are called peripheral blood stem cells (PBSCs). Although very few cells in the periphery (outside the bone marrow space) are PBSCs, their numbers can be increased through administering medications such as growth factors (such as G-CSF [filgrastim]) chemotherapy, and agents such as Mozobil® (plerixafor injection), which will be described in Chapters 2 and 3. Mozobil is a drug that in combination with G-CSF increases stem cells in the blood that can be collected for autologous SCT in patients with non-Hodgkin’s lymphoma or multiple myeloma. Mozobil is not intended for HSCT mobilization and collection in patients with leukemia.

What Is a Stem Cell Transplant?
An SCT is the infusion of bone marrow or PBSCs into your bloodstream. The stem cells then travel through the blood to the bone marrow, where they take up residence. These cells then grow and divide to produce mature RBCs, WBCs, and platelets.

When you receive stem cells obtained from the bone marrow, you are said to be undergoing a bone marrow transplant (BMT). When you receive stem cells obtained from the peripheral blood, you are said to be undergoing a peripheral blood stem cell transplant (PBSC). These terms are often used interchangeably by your healthcare team.

Indication
Mozobil® (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma (NHL) and multiple myeloma (MM).

Important Safety Information for Mozobil
- Severe, life-threatening allergic reactions (anaphylaxis) can happen in people who take Mozobil. Tell your doctor right away if you experience hives (itchy raised bumps), eye swelling, or trouble breathing.
- Mozobil is not intended for hematopoietic stem cell transplantation (HSCT) mobilization and collection in patients with leukemia.

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Types of Transplant
There are several different types of SCT. Stem cells can be collected from yourself, an identical twin, or from a donor who may be related or unrelated to you. If you donate your own stem cells for use in transplant, it is referred to as an **autologous stem cell transplant**. A small proportion of patients will have an identical twin to serve as a donor. Transplantation of these cells is called a **syngeneic stem cell transplant**. Finally, transplantation of stem cells from either a relative or an unrelated volunteer donor from one of the donor registries worldwide is termed an **allogeneic stem cell transplant**. The focus of this booklet will be autologous stem cell transplants.

**Autologous Stem Cell Transplant**
Autologous stem cell transplant is used to treat types of cancer that do not involve the bone marrow or diseases that affect the bone marrow but are in remission (no detectable disease), such as lymphoma, or have little detectable disease, such as multiple myeloma.

Patients with multiple myeloma have been shown to benefit from two transplants, called **tandem autologous transplant** or **double autologous transplant**. A larger number of stem cells is collected before the initial transplant and approximately half of the cells are infused for each transplant. The second transplant is performed after recovery from the first procedure.

**Why Are Stem Cell Transplants Performed?**
The basic idea behind an autologous stem cell transplant is to allow administration of higher chemotherapy and/or radiation therapy doses to kill rapidly dividing cancerous cells and to make room for new, healthy cells. Although these anticancer treatments are among the most effective available, they do not have a precise aim and can destroy rapidly dividing normal cells as well. A stem cell transplant enables the patient to produce new blood cells to replace those destroyed during treatment.

**Stem Cell Mobilization and Collection**
In order to undergo autologous transplant, you must have enough stem cells collected to proceed to transplant. These stem cells are collected before you receive high doses of chemotherapy and/or radiation. The cells are then preserved, frozen, and stored until the time of transplant. The **Stem Cell Transplant Process** on page 2 describes the events and timing of stem cell transplant.

**Apheresis** (ay-fur-EE-sis) is the process by which stem cells that circulate in the blood are separated from the other components of the bloodstream and collected for reinfusion at a later date. Under normal circumstances, stem cells make up only a small portion of the cells found in the blood. However, they can be stimulated to move into the bloodstream in a process called **mobilization** where they can be collected.

**Stem Cell Mobilization**
Stem cell mobilization is a process whereby stem cells are stimulated to move out of the bone marrow space (ie, the hip bones and the chest bone) into the bloodstream. There are 3 main methods of mobilization that will be discussed in more detail in Chapters 2 and 3.

On some occasions, too few stem cells are collected from the peripheral blood, which would prevent you from going forward to transplant. In these cases, you would generally take a short break before another mobilization attempt is made, termed **remobilization**.

**Indication**
Mozobil® (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

**Important Safety Information for Mozobil**
- Mozobil in combination with G-CSF increases circulating white blood cells (WBCs). Your WBC counts will be monitored.
- Thrombocytopenia (a decrease in the number of platelets circulating in the blood) has been observed in patients receiving Mozobil. Your platelet counts will be monitored.
**Stem Cell Collection**

In the past, a bone marrow harvest was the only way to collect stem cells for transplant. Today, it is now possible to collect stem cells from the peripheral blood (ie, from the bloodstream), a process that is easier on you and is generally preferred.4

**Collecting Stem Cells From the Bone Marrow**

Bone marrow harvesting/collection typically occurs in a hospital operating room under general anesthesia. Your doctor inserts a hollow needle into the marrow space of your hip and draws (“aspirates”) the cells from the marrow into a syringe until a target cell number is reached. Once collected, the removed bone marrow is processed and frozen.1 Side effects from this procedure may include temporary bone pain or stiffness.7

**Collecting Stem Cells From the Peripheral Blood**

During PBSC collection, you will be connected to an apheresis machine, also known as a cell separator, via a central venous catheter (CVC) (also known as a central venous line) or another large catheter that may be specially inserted for the procedure. The steps in this process are as follows1:

- Blood leaves your body through the catheter and enters the machine
- The machine separates and collects the stem cells
- Remaining blood components are returned to your body through the catheter

The side effects that occur during the preparative regimen may be similar to or more severe than those you experienced with standard-dose chemotherapy or standard radiation during treatment for your disease. Your transplant team will prescribe chemotherapy medicines depending on your disease and other factors. The preparative regimen destroys both cancer cells and normal blood-producing cells. In order to help your blood counts recover following the preparative regimen, you will undergo an autologous stem cell transplant.1

Only a small amount of blood is inside the machine at any time, and this procedure does not result in anemia. A blood thinner called citrate is slowly added to your blood during apheresis to prevent blood clotting. Citrate may lead to a reduction in your body’s calcium levels, with possible side effects including slight tingling around your mouth, chest vibrations, and a cold sensation. Your doctor or healthcare provider may prescribe a calcium replacement to help avoid these symptoms.7 Apheresis is a continuous process that takes approximately 4-6 hours to complete each day.1 Repeated collections on subsequent days may be necessary to collect enough stem cells to proceed to transplant.

**Stem Cell Freezing and Storage**

After each apheresis procedure, your stem cells are processed, frozen (also called cryopreservation), and stored for future use after you have received high-dose chemotherapy and/or radiation. During the freezing process, a chemical called dimethylsulfoxide (DMSO) is mixed with the stem cells to protect the cells during freezing.

**Pretransplant Chemotherapy and/or Radiation**

After the stem cells are collected, or at some later date, you will receive high-dose chemotherapy and/or radiation therapy, termed the “preparative regimen” or “conditioning regimen.” These higher doses of chemotherapy and radiation are intended to kill any remaining cancer cells and make a space for your new cells to live.1
Stem Cell Transplant

Once the chemotherapy drugs have been cleared or removed from your body, you will be ready to receive your stem cells. On the day of transplant, cells are thawed, then taken to the bedside and infused.\(^8\) Infusion times range from 30 minutes to 5 hours, depending upon the volume of cells to be infused.\(^1\) During, and for a period after the infusion, you may experience and will be checked frequently for signs of fever, chills, hives, a fall in blood pressure, and/or shortness of breath. These side effects are rare and usually mild.\(^8\) Additionally, some patients may feel nauseated or vomit during the procedure due to the DMSO that was used to preserve the stem cells during the freezing process. DMSO has a characteristic garlic odor that may persist for a number of days. Additionally, DMSO may result in temporary changes in taste.\(^8\) For more information on some potential stem cell transplant side effects, please see the table below. You should discuss what side effects to expect with your transplant team.

Common Side Effects Experienced During the Different Parts of the Transplant Process\(^7-13\)

<table>
<thead>
<tr>
<th>Stage of Transplant</th>
<th>Potential Side Effects</th>
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</table>
| **Mobilization and collection** | - Bone pain due to growth factors  
- Dizziness and tingling during apheresis  
- Chills, tremors, and muscle cramps  
- Low blood calcium  
- Pain or bleeding at insertion site of catheter  
- Infection around the site of catheter  
- Blood clots around catheter (occasionally)  
- Bloodstream infection  
- Fatigue/tiredness  
- Injection site reactions  
- Allergic reactions |
| **Preparative regimen** | - Nausea  
- Vomiting  
- Diarrhea  
- Mouth sores (mucositis)  
- Skin rashes  
- Hair loss  
- Infection  
- Fatigue/tiredness  
- Anemia  
- Bleeding  
- Organ toxicity and failure (heart, liver, kidneys, lung) |
| **Stem cell infusion** | Reactions to DMSO  
- Common  
  - Nausea  
  - Vomiting  
  - Abdominal cramping  
  - Garlic aftertaste  
  - Garlic smell  
- Rare  
  - Low blood pressure  
  - Rapid heartbeat  
  - Shortness of breath |
| **Engraftment and recovery** | - Increased risk of infection, bruising, and/or bleeding until engraftment is complete  
- Fatigue/tiredness |

DMSO, dimethylsulfoxide.

Engraftment

As soon as your stored stem cells are infused, they travel through your bloodstream to the bone marrow space in a process called homing. Even though the stem cells start the homing process right away, it will be approximately 8 to 30 days before these infused cells are able to mature and produce healthy new blood cells, a process called engraftment.\(^1\)

One of the first signs of engraftment is that your neutrophil count increases. Neutrophil engraftment is defined as the first day of 3 consecutive days where the neutrophil count (absolute neutrophil count) is 500 cells/mm\(^3\) (0.5 \(\times\) 10\(^9\)/L) or greater.\(^14\) Platelet engraftment is generally defined as a platelet count of more than 20,000/mm\(^3\) (20 \(\times\) 10\(^9\)/L) without the need for any platelet transfusions.\(^14\) Until engraftment occurs, you may be at risk of developing an infection and may find that you bruise and/or bleed more easily.\(^8\) Your doctor or healthcare provider will watch you very closely during this time.

During the entire transplant process, it is important to maintain your nutrition, physical activity, and overall health. Talk to members of your transplant team to determine what is an appropriate diet and level of activity for you.
Chapter 2: Stem Cell Mobilization

Preferred Characteristics of a Mobilization Regimen

Stem cells exist primarily in the bone marrow. As explained in Chapter 1, mobilization is necessary to drive these stem cells to the bloodstream to collect enough to enable you to proceed to transplant. The preferred characteristics of a mobilization regimen include:

- Mobilizing enough stem cells for transplant
- Minimizing the number of days you are on the apheresis machine
- Collecting stem cells that allow quick and long-lasting (often termed “durable”) recovery of RBCs, WBCs, and platelets when they are reinfused into your body

Factors That May Affect the Mobilization of Stem Cells

Some patients are unable to collect the target number of stem cells with mobilization strategies. There are a number of reasons for not collecting enough stem cells and these may include:

- Increased age
- Receipt of prior treatment regimens and cycles

If you do not collect the required number of cells, you may not be able to proceed to your preparative regimen as prescribed by your doctor.

Number of Stem Cells for Transplantation

It is crucial to collect a minimum number of stem cells for transplant to enable these cells to grow and mature into the functional and useful components of your bloodstream. Most transplant physicians prefer to have at least 2 million stem cells per kilogram of your body weight before proceeding to transplant. This is the minimum number of cells in most situations, and your transplant doctor may aim for more stem cells for a single transplant. It is important that you speak with your transplant team regarding your individual stem cell collection target as this can vary according to your disease, transplant center, and ability to collect sufficient cells.

Indication

Mozobil® (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma (NHL) and multiple myeloma (MM).

Important Safety Information for Mozobil

- Cancer cells may be released from the bone marrow and subsequently collected along with your stem cells during apheresis. The potential effects of infusing cancer cells during your transplant have not been well-studied.
- Your spleen may be examined if you experience pain in the left upper stomach area or left shoulder area as these may be signs of an enlarged or burst (ruptured) spleen.

Mobilization Options

Commonly used mobilization strategies include growth factor alone or chemotherapy followed by growth factor (chemomobilization).

Stem cell mobilization with growth factors

Growth factors are proteins that control the growth, division, and maturation of cells, including blood cells. As discussed in Chapter 1, there are 2 growth factors approved by the FDA that act to increase the number of circulating WBCs in the body. Your doctor or healthcare provider will talk to you about the growth factor they prefer to use and the administration process.

Stem cell mobilization with chemotherapy followed by growth factors

It has been known for more than 30 years that the number of stem cells increase in the blood during the recovery period after chemotherapy. The reason for this is unknown, but it has led to studies comparing chemotherapy followed by growth factor (chemomobilization) to growth factor alone for stem cell mobilization. The mobilization regimen used by your doctor may be specifically tailored to your disease and other factors.
Mozobil® (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma (NHL) and multiple myeloma (MM).

**Important Safety Information for Mozobil**

- Severe, life-threatening allergic reactions (anaphylaxis) can happen in people who take Mozobil. Tell your doctor right away if you experience hives (itchy raised bumps), eye swelling, or trouble breathing.

- Mozobil is not intended for hematopoietic stem cell transplantation (HSCT) mobilization and collection in patients with leukemia.

- Mozobil in combination with G-CSF increases circulating white blood cells (WBCs). Your WBC counts will be monitored.

- Thrombocytopenia (a decrease in the number of platelets circulating in the blood) has been observed in patients receiving Mozobil. Your platelet counts will be monitored.

- Cancer cells may be released from the bone marrow and subsequently collected along with your stem cells during apheresis. The potential effects of infusing cancer cells during your transplant have not been well-studied.

- Your spleen may be examined if you experience pain in the left upper stomach area or left shoulder area as these may be signs of an enlarged or burst (ruptured) spleen.

- Mozobil may harm the unborn child when administered to a pregnant woman. Scientific studies have shown that Mozobil causes harm to unborn animals. The safety of Mozobil in pregnant women has not been established in clinical trials. If you are of childbearing potential you should be advised to avoid becoming pregnant while receiving treatment with Mozobil. If this drug is used during pregnancy, or if you become pregnant while taking this drug, you should be apprised of the potential hazard to the unborn child.

- The most common adverse reactions (occurring in greater than or equal to 10% of patients) during HSC mobilization and apheresis were: diarrhea (37%), nausea (34%), tiredness (fatigue) (27%), injection site reactions (34%), headache (22%), pain in your joints (arthralgia) (13%), dizziness (11%), and vomiting (10%).

Please see additional Important Safety Information on page 8 and full Prescribing Information at http://products.sanofi.us/Mozobil/mozobil.html
Chapter 3: Introduction to Mozobil® (plerixafor injection)

Approved Uses
Mozobil is approved by the United States Food and Drug Administration to be used in combination with another agent (G-CSF) for mobilization of hematopoietic stem cells into the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma or multiple myeloma.3

The safety and efficacy of Mozobil in children has not been established in clinical studies.3

Benefits of Mozobil
Clinical studies have demonstrated several benefits to using Mozobil with G-CSF compared to G-CSF alone for the mobilization of stem cells. These include:

- Higher success rates for mobilizing stem cells
  - More patients achieved the minimum and target number of stem cells for a transplant26,27
  - More patients collected stem cells and went on to stem cell transplant27
- Potential for fewer apheresis procedures26,27
- Nearly all multiple myeloma and non-Hodgkin’s lymphoma patients receiving cells mobilized by either Mozobil in combination with G-CSF or by G-CSF alone had successful engraftment26,27

Administration and Timing
Mozobil is to be administered as a subcutaneous injection (under the skin) approximately 11 hours prior to the start of each apheresis session for up to 4 consecutive days.3

Mozobil is to be used in combination with G-CSF. Granulocyte colony-stimulating factor is administered in the morning daily for 4 days prior to the first dose of Mozobil and on each morning prior to apheresis.3

Mozobil is removed from the body by the kidneys and excreted in the urine.3 Your dose of Mozobil will be tailored to your kidney function by your doctor or healthcare provider, if necessary.3

For further information, go to www.mozobil.com or call 1-877-4MOZOBIL (1-877-466-9624).
**How Mozobil® (plerixafor injection) Works (Mechanism of Action)**

Mozobil releases the stem cells from the bone marrow into the bloodstream. Specifically, Mozobil binds to a protein on the surface of stem cells called CXCR4. By binding to CXCR4, Mozobil disrupts the bonds (with SDF-1α) that normally keep stem cells anchored in the bone marrow, allowing their release into the bloodstream.\(^{28,29}\) (See pictures to the right.) This enables your healthcare team to collect more stem cells during apheresis.\(^3\)

**Indication**

Mozobil (plerixafor injection) is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

**Important Safety Information for Mozobil® (plerixafor injection)**

- Mozobil may harm the unborn child when administered to a pregnant woman. Scientific studies have shown that Mozobil causes harm to unborn animals. The safety of Mozobil in pregnant women has not been established in clinical trials. If you are of childbearing potential you should be advised to avoid becoming pregnant while receiving treatment with Mozobil. If this drug is used during pregnancy, or if you become pregnant while taking this drug, you should be apprised of the potential hazard to the unborn child.

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What is Mozobil® (plerixafor injection)?
Mozobil is a drug that in combination with G-CSF increases stem cells in the blood that can be collected for autologous SCT in patients with non-Hodgkin’s lymphoma or multiple myeloma.

What does Mozobil do?
Mozobil works by releasing stem cells from the bone marrow, making them available to collect from your bloodstream. Normally, these stem cells are present in the bloodstream in very low numbers since they are more likely to stay in the bone marrow. Mozobil increases the levels of stem cells in the blood by preventing them from remaining anchored inside the bone marrow space.

Why did my doctor give me Mozobil + G-CSF?
Your doctor gave you Mozobil because you have been diagnosed with non-Hodgkin’s lymphoma or multiple myeloma and are expected to eventually undergo an autologous SCT. As your own cells will be used for your SCT, your transplant team must collect them before you receive treatment for your cancer and keep them until your transplant. Mozobil helps to release your stem cells from the bone marrow into the bloodstream so they can be collected for transplant. Infusing your collected stem cells will help your blood counts rebound after receiving high-dose chemotherapy with or without radiation.

When will I receive Mozobil + G-CSF and for how long?
Mozobil will be administered approximately 11 hours prior to each apheresis, up to a total of 4 days.

In addition to receiving Mozobil, you will receive G-CSF each morning for 4 days prior to the start of Mozobil and on each morning of apheresis.

Where will I receive Mozobil?
You are most likely to receive Mozobil at your transplant center or hospital, depending on hours of operation.

Is there any reason that I should not take Mozobil?
- If you have a history of allergy to Mozobil. Severe allergic reactions have occurred with use of Mozobil.
- If you have leukemia. Taking Mozobil to increase stem cells while you have leukemia may increase the number of leukemic cells in the bloodstream
- If you are pregnant or trying to become pregnant. Mozobil may cause harm to an unborn fetus when administered to pregnant women. Women of childbearing potential should not become pregnant while receiving treatment with Mozobil
- You should talk to your doctor or healthcare provider if you are a nursing mother. It is not known whether Mozobil is excreted in human milk
- You should talk to your doctor or healthcare provider if you are under the age of 18. The safety and efficacy of Mozobil in pediatric patients has not been established in controlled studies

Please see additional Important Safety Information on page 8 and full Prescribing Information at http://products.sanofi.us/Mozobil/mozobil.html
Are there any potentially serious side effects of Mozobil® (plerixafor injection)?

Severe, life-threatening allergic reactions (anaphylaxis) can happen in people who take Mozobil. Tell your doctor right away if you experience hives (itchy raised bumps), eye swelling, or trouble breathing.

Patients taking Mozobil may experience increases in leukocytes (leukocytosis), an increased number of WBCs; or a decrease in the number of platelets circulating in their blood (thrombocytopenia). While you are receiving Mozobil injections, your doctors and healthcare providers will monitor your blood cell counts closely to manage these side effects.

The size of your spleen may increase while you are taking Mozobil. Spleen enlargement can result in the spleen bursting (rupture), which may cause death. Signs of an enlarging spleen include pain in the upper left-hand region of your stomach or near the tip of your shoulder. Let your doctor know immediately if you have any of these symptoms.

Cancer cells may be released from the bone marrow and subsequently collected along with your stem cells during apheresis. The potential effects of infusing cancer cells during your transplant have not been well studied.

Tell your doctor or healthcare provider if you develop any other potential side effects.

Indication

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Mozobil is approved by the United States Food and Drug Administration to be used in combination with another agent (G-CSF) for mobilization of hematopoietic stem cells into the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma or multiple myeloma.³

What are some of the potential side effects of Mozobil?

While being treated with Mozobil, some of the most common side effects you may experience include diarrhea, nausea, vomiting, fatigue, redness and swelling at the injection site, pain in your joints, headache, and dizziness. Most of these side effects may improve or disappear after you finish receiving Mozobil injections.

Less common side effects that were reported in some patients who have taken Mozobil include abdominal pain and swelling, excessive sweating, dry mouth, redness of the skin, stomach discomfort, constipation, indigestion, muscle or bone pain, a reduced sensation to stimuli such as touch, or a general feeling of being unwell.

You should also let your doctor know if you feel light-headed or have difficulty breathing shortly after your Mozobil injection as these could be signs of adverse reactions to Mozobil. Some patients have experienced a sudden drop in their blood pressure when standing from a sitting position (orthostatic hypotension). Do not stand up abruptly on days when you are taking Mozobil. This usually occurs within 1 hour of Mozobil administration.

Please see additional Important Safety Information on page 8 and full Prescribing Information at http://products.sanofi.us/Mozobil/mozobil.html
Homing – occurs when new, infused stem cells begin traveling through the circulatory system and to the bone marrow

Growth factors – substances that stimulate cell growth

Hematopoietic – relating to the formation of blood or blood cells

Anemia – a deficiency in RBCs, leading to tiredness and lack of energy

Apheresis – the process of collecting blood from a donor, removing one or more blood components (plasma, blood platelets, or WBCs), and then returning the remaining blood back to the donor through transfusion

Autologous stem cell transplant – stem cell transplant using a patient’s own stem cells

Bone marrow – a soft sponge-like tissue in the middle of all your bones that contains lots of blood vessels, RBCs, most WBCs, and platelets

Bone marrow transplant (BMT) – infusion of stem cells obtained from the bone marrow

Central venous catheter (CVC) – a tubular device typically inserted into a large vein in the neck. A CVC can also be inserted into the chest or the groin. A CVC is used to administer multiple medications, intravenous fluids, and to draw blood samples to perform tests

Central venous line (CVL) – see “Central venous catheter”

Chemomobilization – using chemotherapy (typically followed by growth factor) as a catalyst to move stem cells from bone marrow to circulating blood

Conditioning regimen – chemotherapy or radiation that is administered prior to transplant to kill any remaining cancer cells and to make room for new stem cells

Cryopreservation – the process by which cells or whole tissue are preserved by cooling to subzero temperatures

Dimethylsulfoxide (DMSO) – a chemical preservative used to protect stem cells during the freezing process, preventing the cells from collapsing and dying

Double autologous transplant – also known as a tandem autologous transplant; a patient undergoing 2 planned autologous stem cell transplants sequentially, using their own stem cells collected before the initial transplant

Engraftment – the process by which collected stem cells received during transplant start to grow and make new blood cells. The definition of engraftment in transplant is very specific and relates to neutrophil and platelet count recovery. Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (absolute neutrophil count) is 500 cells/mm³ (0.5 x 10⁹/L) or greater. Platelet engraftment is defined as 20,000/mm² (20 x 10⁹/L) unsupported by a platelet transfusion

General anesthesia – a process induced by drug therapy where a patient’s sensation is blocked. In this situation a patient is not awake (conscious) and will not feel any sensations

Growth factors – also known as WBCs; these cells fight the bacteria, viruses, fungi, and other substances that cause infection

Leukocytosis – a condition in which the patient has elevated WBCs in the blood

Mobilization – the process of stimulating stem cells to move out of the bone marrow and into the bloodstream for collection

Mucositis – the inflammation of the mucous membranes lining the digestive tract including the mouth, the windpipe, the stomach, and the anus

Neutrophils – the chief WBCs that consume foreign materials in the body

Orthostatic hypotension – a sudden fall in blood pressure when a person stands up from the sitting position

Peripheral blood stem cells (PBSCs) – stem cells that leave the bone marrow and circulate in the bloodstream

Peripheral blood stem cell transplant (PBSCT) – infusion of stem cells obtained from the peripheral blood

Platelet – a tiny disc-shaped blood fragment that assists in forming blood clots; essential to prevent excessive bleeding

Preparative regimen – chemotherapy or radiation that is administered prior to transplant to kill any remaining cancer cells and to make room for new stem cells

Red blood cells (RBCs) – cells that carry oxygen to the body’s tissues and carbon dioxide away from the tissues

Remission – a decrease in or disappearance of signs and symptoms of cancer. In partial remission, some, but not all, signs and symptoms of cancer have disappeared. In complete remission, all signs and symptoms of cancer that can be detected with modern technology have disappeared, although cancer still may be in the body

Remobilization – the process of mobilization following failure of an earlier procedure

Spleen – an oblong-shaped organ situated between the heart and stomach that plays a role in the final destruction of RBCs, filtration and storage of blood, and production of lymphocytes

Stem cells – very young cells that mature into the functional components of your bloodstream like RBCs, WBCs, and platelets and help you recover from the marrow suppressive effects of high doses of chemotherapy and radiation

Stem cell transplant (SCT) – an infusion of stem cells into a recipient’s bloodstream; in cancer patients, usually performed after high intensity chemotherapy and/or radiation in order to restore healthy levels of blood cells

Subcutaneous injection – an injection delivered under the skin

Syngeneic stem cell transplant – transplant using stem cells from an identical twin

Tandem autologous transplant – see “Double autologous transplant”

Thrombocytopenia – a condition in which there are not enough platelets in the blood. Thrombocytopenia is likely to occur following a stem cell transplant and increases your chance of bleeding

White blood cells (WBCs) – cells that fight bacteria, viruses, and fungi that can cause infection
References


22. Giaspy JA. Economic considerations in the use of peripheral blood progenitor cells to support high-dose chemotherapy. Bone Marrow Transplant. 1999;23(suppl 2):S21-S27.


### Mobilization Calendar

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Please see additional Important Safety Information on page 8 and full Prescribing Information at [http://products.sanofi.us/Mozobil/mozobil.html](http://products.sanofi.us/Mozobil/mozobil.html)
Indication

Mozobil® (plerixafor injection), is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin’s lymphoma (NHL) and multiple myeloma (MM).

Important Safety Information for Mozobil

- Severe, life-threatening allergic reactions (anaphylaxis) can happen in people who take Mozobil. Tell your doctor right away if you experience hives (itchy raised bumps), eye swelling, or trouble breathing.
- Mozobil is not intended for hematopoietic stem cell transplantation (H SCT) mobilization and collection in patients with leukemia.
Additional Resources

- American Cancer Society: http://www.cancer.org
- American Society for Blood and Marrow Transplantation (ASBMT): http://www.asbmt.org
- Blood & Marrow Transplant Information Network (BMT InfoNet): http://www.bmtinfonet.org
- Center for International Blood & Marrow Transplant Research (CIBMTR): http://www.cibmtr.org
- International Myeloma Foundation: http://www.myeloma.org
- Leukemia & Lymphoma Society: http://www.lls.org
- Leukemia Research Foundation: http://www.leukemia-research.org
- Lymphoma Research Foundation: http://www.lymphoma.org
- Multiple Myeloma Research Foundation: http://www.themmrf.org
- National Bone Marrow Transplant Link (nbmtLINK): http://www.nbmtlink.org
- National Marrow Donor Program: http://www.marrow.org

Mozobil® (plerixafor injection) Patient Education CD