

Preparing for your autologous stem cell transplant with APHEXDA

A guide for patients with multiple myeloma and their caregivers

What is APHEXDA?

APHEXDA is a prescription medication used with filgrastim (G-CSF) to move hematopoietic stem cells from the bone marrow to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.

It is not known if APHEXDA is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

Who should not use APHEXDA?

Do not use APHEXDA if you have a history of serious allergic reactions to motixafortide (the active ingredient in APHEXDA).

Understanding what's ahead

You've reached an important step in your journey with multiple myeloma. You and your treatment team, which includes the doctors and nurses involved in your care, decided it is time to prepare for an autologous stem cell transplant, including treatment with APHEXDA, a hematopoietic stem cell mobilizer.



APHEXDA is a prescription medication used with filgrastim (sometimes called G–CSF) to move hematopoietic stem cells from the bone marrow to the peripheral blood for collection during apheresis and subsequent autologous transplantation in patients with multiple myeloma.

Do not use APHEXDA if you have a history of serious allergic reactions to motixafortide (the active ingredient in APHEXDA).

The purpose of this guide is to help prepare you for what's to come. You'll learn more about the transplant process and how APHEXDA can help. You also will have a space to write down questions or notes to discuss with your treatment team, and a calendar to help keep track of important dates.



This guide is meant to be educational and helpful, but it is not intended to provide medical advice. Remember, your treatment team should always be your primary source of information and guide treatment decisions

The 3 main parts of your transplant

Your transplant is a multi-step procedure often used to treat multiple myeloma. This procedure takes place at a hospital or transplant center.



Your own stem cells will be collected from your blood in a process called apheresis, then stored for your transplant. Some centers collect enough cells for a second transplant at a later time, if needed



See pages 4 and 5 for more about stem cells and apheresis.



You will receive chemotherapy or radiation to kill the cancer cells



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Once chemotherapy or radiation is complete, your stem cells will be transplanted, or put back, into your body to replace any stem cells that may have been impacted by treatment

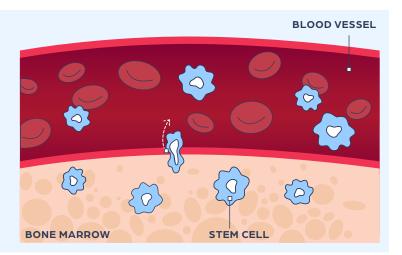




The transplanted stem cells will travel to your bone marrow and restore the marrow's ability to make healthy blood cells, which your doctor may refer to as engraftment

Your transplant starts with your stem cells

Stem cells are made deep in your bone marrow. Your stem cells will need to move from the bone marrow to the bloodstream for collection during apheresis. This process is called stem cell mobilization.



Some things can make stem cell mobilization more difficult, such as:



Advanced age

As you get older, the number of stem cells that can be used for transplant goes down



Previous treatment

While there have been advancements in treatment options, taking them before your transplant may lower the number of stem cells collected for transplant



Other risk factors

If you were not able to collect enough cells for transplant before, or had certain previous therapies, you may not mobilize the target number of stem cells

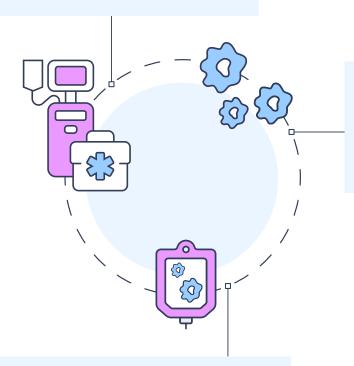


The success of your transplant often depends on having enough stem cells in the blood to be collected during apheresis

Apheresis is essential for your transplant

During apheresis, stem cells are collected from your blood. This is also called harvesting stem cells. An apheresis session takes about 5 hours. Daily apheresis sessions may occur until your target goal is reached.

Prior to your first apheresis session, a tube called a central venous catheter (CVC) will be placed into a large vein to collect the blood. On the day of apheresis, you will sit close to an apheresis machine



The apheresis machine takes blood from your body, separates out the stem cells, and sends the remaining blood back into your body

The collected stem cells will be frozen and stored until it is time for them to be transplanted back into your body



The goal of apheresis is to collect enough stem cells for your transplant based on the target amount set by your treatment team

Target stem cell collection goals are determined by your treatment team

Each transplant center has a different goal when it comes to the targeted amount of stem cells to be collected during apheresis. Some doctors choose to collect enough stem cells to perform 2 transplants, as recommended by professional association guidelines.

GUIDELINE RECOMMENDATIONS FOR STEM CELL COLLECTION TARGETS

ORGANIZATION	MINIMUM	RECOMMENDED	HIGHER	
International Myeloma Working Group	2 million CD34+ cells/kg	4-6 million CD34+ cells/kg	8–10 million CD34+ cells/kg (minimum of 4 million) to make sure you have enough cells for 2 transplants, if needed	
American Society for Transplantation and Cellular Therapy	2 million CD34+ cells/kg	3–5 million CD34+ cells/kg	6-10 million CD34+ cells/kg (double the recommended target) if multiple transplants are planned	

These recommendations are used to guide stem cell collection goals, but everyone's situation is different. Your treatment team will decide what your goal should be based on your individual situation. Once you've talked to your treatment team about their goals for you, use the space below to write down what you discussed.



To reach your stem cell collection goal, it may take 1 or more apheresis sessions

That's where APHEXDA® (motixafortide), a stem cell mobilization therapy for patients with multiple myeloma, comes in

Your doctor chose APHEXDA, a prescription medication, used with daily filgrastim to help mobilize your stem cells from the bone marrow to the bloodstream before your apheresis session.



APHEXDA, in combination with filgrastim, was designed to help move your stem cells so they can be available for collection, and to minimize apheresis days.



APHEXDA was approved by the Food and Drug Administration (FDA) based on the safety profile and efficacy results from a clinical study

SELECT IMPORTANT SAFETY INFORMATION

What are the possible side effects of APHEXDA?

APHEXDA may cause serious side effects including:

- Anaphylactic shock and hypersensitivity reactions have occurred in patients taking APHEXDA.
 - Your doctor should administer medications, including antihistamines, approximately 30–60 minutes before administering APHEXDA.
 - You should be monitored for 1 hour for signs and symptoms of these reactions.
 - Tell your doctor immediately if you have any side effects including difficulty breathing, itching, flushing (redness in the face), hives (itchy raised bumps), rash, redness, vomiting, nausea, and chills.
 - Tell your doctor about all medications you are taking before starting APHEXDA. Some medications you are currently prescribed may lower your blood pressure further in the event you have a reaction.

Know what to expect leading up to APHEXDA® (motixafortide) + filgrastim and apheresis

Before your first apheresis session, you will receive filgrastim injections. These are meant to help get your stem cells out of your bone marrow and into your bloodstream for collection.

Every day for 4 days before apheresis

You will receive 1 filgrastim injection (in the AM), including the day you receive APHEXDA

30-60 minutes before APHEXDA on Day 4

You should receive premedications to help reduce the risk of hypersensitivity reactions and injection site reactions

You will receive your APHEXDA injection 10–14 hours before apheresis (likely the night before)

- APHEXDA is given as a slow, 2-minute injection under the skin
- Your dose will be based on your body weight
- You may need more than 1 injection to get a full dose



For 1 hour after APHEXDA

Your treatment team should monitor you for potential side effects. APHEXDA should only be given in a place where your treatment team can immediately address any side effects that may occur

10-14 hours after APHEXDA (the next day)

Your apheresis session will begin. It should take about 5 hours. You will be seated in a chair and your treatment team should check on you frequently



During the apheresis session, you can rest, read, or stream your favorite show. You will want to wear comfortable, loose clothing and bring any charging cords.

After apheresis

Your treatment team should be able to tell you how many stem cells were collected during the session. Based upon the amount, your treatment team will determine whether or not you will need additional apheresis sessions

 Even if you need a second apheresis session, you will not need another dose of APHEXDA. If needed, a second dose of APHEXDA can be given to you 10–14 hours before a third apheresis session. Filgrastim will continue to be given once daily in the AM, within 1 hour before each apheresis session, if more sessions are needed

BioLineRx Connect is here for you

BioLineRx is committed to helping you receive access and appropriate financial support once APHEXDA® (motixafortide) has been prescribed by your doctor. BioLineRx Connect is here to support you by offering the following services:



Getting your APHEXDA

This includes talking to your insurance company, if necessary, to find out if APHEXDA is covered, and providing information about the prior authorization process



Financial Assistance

APHEXDA can be provided at no cost if you are uninsured or lack coverage, qualify for assistance with out-of-pocket drug costs, and are eligible* for this service



Additional support

BioLineRx Connect Program Specialists can identify and provide information on additional support services for you and your caregiver

*Eligibility criteria and program maximums apply. Please call the BioLineRx Connect program for full Terms and Conditions.



BioLineRx Connect Program Specialists are here to help you Monday to Friday, 9 AM to 5 PM ET 1–866–524–6546

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 - Tell your doctor about all medications you are taking before starting APHEXDA. Some medications you are currently prescribed may lower your blood pressure further in the event you have a reaction.
- Injection site reactions including pain, redness, and itching have occurred.
 - Administration of a pain medication, such as acetaminophen, before treatment with APHEXDA is recommended.
 - Your doctor may also treat pain postdose, as needed.

What are the possible side effects of APHEXDA® (motixafortide)? (CONTINUED)

- APHEXDA should not be used in patients with leukemia because of the risk of cancer cells being released from the bone marrow.
- Increases in circulating white blood cells have occurred when APHEXDA is used in combination with filgrastim. Your white blood cell counts will be monitored.
- Cancer cells may be released from bone marrow and subsequently collected along with your stem cells in the apheresis product when APHEXDA is used in combination with filgrastim. The effect of potential reinfusion of tumor cells has not been well-studied.

The most common side effects (occurring in greater than 20%) in patients treated with APHEXDA were injection site reactions (73%) including pain, redness, and itching at the injection site; itching (38%); flushing (33%); back pain (21%).

These are not all the possible side effects of APHEXDA. For more information, ask your healthcare provider. Call your doctor for medical advice about side effects. **You may report negative side effects to FDA at 1–800–FDA–1088 or <u>www.fda.gov/medwatch</u>. You may also call BioLineRx USA, Inc. at 1–800–574–9978.**

What should I tell my healthcare provider before receiving APHEXDA?

Before receiving APHEXDA, tell your healthcare provider:

- All your medical conditions.
- If you are pregnant or plan to become pregnant. Harm to the unborn fetus can occur if APHEXDA is used during pregnancy. Your healthcare professional should verify if you are pregnant before starting APHEXDA. If you are a female of childbearing potential, use an effective form of contraception during treatment with APHEXDA and for 8 days after the last dose.
- If you are breastfeeding or plan to breastfeed. Breastfeeding is not recommended during treatment with APHEXDA and for 8 days after the last dose.
- All the medications you are taking, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Keep track of where your stem cells are stored

The stem cells collected during apheresis can be stored for later use. It may be helpful to keep track of where they are. Use the space below to write down where your stem cells are being stored and keep it as a record of their location.

STORAGE LOCATION:								
APHERESIS APPOINTMENT SCHEDULER								
MONTH:								
SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY		

