


APHEXDATM 
motixafortide
for injection
36.5 mg/mL

Dosing and Administration Guide

APHEXDA is indicated in combination with filgrastim* to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.

*Commonly referred to as granulocyte colony-stimulating factor (G-CSF).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

APHEXDA is contraindicated in patients with a history of serious hypersensitivity reactions to motixafortide.

Please see additional Important Safety Information on [page 10](#) and full [Prescribing Information](#).

This guide was developed by BioLineRx USA, Inc. and is for US healthcare professionals only.

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Dosing Schedule

APHEXDA should be administered:

- In the evening on the fourth day of filgrastim administration
- 10–14 hours before starting the first apheresis
- As a slow (approximately 2 minutes per syringe) subcutaneous injection

Additional apheresis sessions

- No additional dose of APHEXDA is needed for a second apheresis
- If needed, a second dose of APHEXDA can be administered 10–14 hours before a third apheresis
- Filgrastim should continue to be administered once daily in the morning 1 hour prior to each apheresis session if additional sessions are needed

					Apheresis	Apheresis (if needed)	Apheresis (if needed)	Apheresis (if needed)
Day	1	2	3	4	5	6	7	8
Filgrastim (10 mcg/kg)	AM	AM	AM	AM	AM	AM	AM	AM
APHEXDA (1.25 mg/kg)				PM		PM (if needed)		

Please see page 4 for premedications to administer prior to administering APHEXDA.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

- **Anaphylactic Shock and Hypersensitivity Reactions:** Anaphylactic shock and hypersensitivity reactions have occurred. Premedicate all patients with a triple drug premedication regimen that includes an H1-antihistamine, an H2 blocker, and a leukotriene inhibitor approximately 30–60 minutes prior to each dose of APHEXDA. Administer APHEXDA in a setting where personnel and therapies are immediately available for treatment of anaphylaxis and other systemic reactions. Monitor patients for 1 hour following APHEXDA administration and manage reactions promptly. Patients receiving negative chronotropic drugs (e.g., beta-blockers) may be more at risk for hypotension in the event of a hypersensitivity reaction and these drugs, when appropriate, should be replaced with non-chronotropic drugs.

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Premedication

Premedicate before each dose of APHEXDA to reduce the risk of hypersensitivity and injection site reactions.

- **Administer the following premedications 30 minutes to 1 hour before injecting APHEXDA:**
 - Diphenhydramine (12.5 mg intravenously or 25 to 50 mg orally, or another H1-antihistamine)
 - H2 blocker (eg, famotidine)
 - Leukotriene inhibitor (eg, montelukast)
- **The addition of an analgesic medication (eg, acetaminophen) is also recommended**

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

- **Injection Site Reactions:** Injection site reactions (73%) including pain (53%), erythema (27%), and pruritus (24%) have occurred. Severe reactions occurred in 9% of patients. Premedicate with an analgesic premedication (e.g., acetaminophen) prior to each APHEXDA dose. Use analgesic medication and local treatments post-dose, as needed.

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Calculating and Preparing the Dose

Calculating dose

- The recommended dose for APHEXDA is 1.25 mg/kg via subcutaneous injection
- Dose is calculated according to the patient's actual body weight
- Formula for calculating the volume of injection (mL):

$$\frac{1.25 \text{ mg/kg} \times \text{Patient weight (kg)}}{36.5 \text{ mg/mL}} = \text{Volume (mL) of injection needed}$$

Getting ready

- Determine the number of vials needed. Each vial delivers 1.7 mL
 - More than 1 vial may be needed for the full dose

Patient's Weight	Number of Vials*
≤50 kg (110 lbs)	1
>50 kg (110 lbs) to ≤100 kg (220 lbs)	2
>100 kg (220 lbs) to ≤150 kg (330 lbs)	3
>150 kg (330 lbs) to ≤200 kg (440 lbs)	4

*Injection volume should be calculated according to the patient's actual body weight. This table should be used as guidance for determining the minimum number of vials needed to provide the calculated dose.

- Remove APHEXDA vial(s) from the refrigerator and allow to reach room temperature at 20 °C to 25 °C (68 °F to 77 °F) for at least 30 minutes before reconstitution

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

- **Tumor Cell Mobilization in Patients with Leukemia:** For the purpose of hematopoietic stem cell (HSC) mobilization, APHEXDA may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, APHEXDA is not intended for HSC mobilization and harvest in patients with leukemia.

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Reconstitution

**APHEXDA must be reconstituted before each use.
Reconstituted solution will contain 36.5 mg/mL APHEXDA.**

- **Reconstitute each vial with 2 mL 0.45% Sodium Chloride Injection, USP at room temperature at 20 °C to 25 °C (68 °F to 77 °F)**
 - Alternatively, each vial can be reconstituted with 1 mL Sterile Water for Injection, USP and 1 mL 0.9% Sodium Chloride Injection, USP
- **Gently swirl and invert for up to 3 minutes slowly until completely dissolved**
- **The reconstituted solution should appear clear and colorless. Do not use if the reconstituted solution is discolored, is cloudy, or contains visible particulates**
- **If needed, store the reconstituted APHEXDA solution refrigerated at 2 °C to 8 °C (36 °F to 46 °F) or at room temperature at 20 °C to 25 °C (68 °F to 77 °F) for up to 24 hours protected from light**

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

- **Leukocytosis:** Administering APHEXDA in conjunction with filgrastim increases circulating leukocytes as well as HSC populations. Monitor white blood cell counts during APHEXDA use.
- **Potential for Tumor Cell Mobilization:** When APHEXDA is used in combination with filgrastim for HSC mobilization, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of potential reinfusion of tumor cells has not been well-studied.

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Administration

- **Give a first dose of APHEXDA the evening of the fourth day of filgrastim mobilization, 10–14 hours before the start of apheresis**
- **Withdraw the required injection volume of APHEXDA from the vial(s) into appropriately sized syringe(s)**
- **Each injection volume should not exceed 2 mL. Divide doses requiring greater than 2 mL into multiple syringes to allow different injection sites**
- **Administer injection into the abdomen, the back or side of the upper arms, or the thighs**
 - As a slow (approximately 2 minutes per syringe) subcutaneous injection
 - Rotate injection sites
 - An injection should never be given into scar tissue or areas that are reddened, inflamed, or swollen
 - If injecting into the abdomen, avoid a 5 cm diameter circle around the navel
 - If more than one injection is needed for a single dose of APHEXDA, the injection sites should be at least 2 cm apart from previous injection locations
- **Discard unused portion of the drug**
- **If a third apheresis is needed, a second dose of APHEXDA can be given 10–14 hours prior**

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

- **Embryo–fetal Toxicity:** Based on its mechanism of action, APHEXDA can cause fetal harm. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating treatment with APHEXDA and advise use of effective contraception during treatment and for 8 days after the final dose.

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Monitoring

- **Monitor patients for signs or symptoms of hypersensitivity reactions for 1 hour following administration of APHEXDA and manage reactions promptly**
- **APHEXDA should only be administered in a setting where personnel and therapies are immediately available for treatment of anaphylaxis and other systemic reactions**

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

The most common adverse reactions (incidence >20%) in patients treated with APHEXDA were injection site reactions [73%, including pain (53%), erythema (27%), pruritus (24%)]; pruritus (38%); flushing (33%); back pain (21%).

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Storage and Handling

APHEXDA for injection is supplied as a white to off-white lyophilized powder in a single-dose vial for reconstitution. Each vial delivers 62 mg motixafortide free base.

Storage

- **Vials should be stored:**
 - Under refrigeration at 2 °C to 8 °C (36 °F to 46 °F)
 - In original carton to protect from light

Handling

- **Discard prepared reconstituted solution after 24 hours storage under refrigeration or at room temperature protected from light**



IMPORTANT SAFETY INFORMATION (CONTINUED)

USE IN SPECIFIC POPULATIONS

Pregnancy: Please see the important information in Warnings and Precautions under Embryo–fetal Toxicity.

Lactation: There are no data on the presence of motixafortide in human milk, the effects on the breastfed child, or the effects on milk production. Advise females that breastfeeding is not recommended during treatment with APHEXDA and for 8 days after the final dose.

Pediatric Use: The safety and effectiveness of APHEXDA have not been established in pediatric patients.

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INDICATION

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ADVERSE REACTIONS

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Please see full [Prescribing Information](#).

REFERENCE: APHEXDA. Prescribing information. BioLineRx Ltd; 2023.



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US-APH-2300021 (v1.0) 09/2023

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