

ELREXFIO™

(elranatamab-bcmm)

INJECTION FOR
SUBCUTANEOUS USE | 44 mg/1.1 mL
76 mg/1.9 mL

Getting Started With ELREXFIO

A guide to understand how ELREXFIO is given, possible side effects, and support available throughout treatment.



What is ELREXFIO?

ELREXFIO is a prescription medication used to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody to treat their multiple myeloma, **and**
- their cancer has come back or did not respond to prior treatment

ELREXFIO was approved based on patient responses and durability of response. There are ongoing studies to confirm its clinical benefit. It is not known if ELREXFIO is safe and effective in children.

SELECTED SAFETY INFORMATION

ELREXFIO may cause side effects that are serious, life-threatening, or can lead to death, including cytokine release syndrome (CRS) and neurologic problems. CRS is common during treatment with ELREXFIO.

Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS or neurologic problems, including:

- fever of 100.4°F (38°C) or higher
- trouble breathing
- chills
- dizziness or light-headedness
- fast heartbeat
- headache
- increased liver enzymes in your blood
- agitation, trouble staying awake, confusion or disorientation, or seeing or hearing things that are not real (hallucinations)
- trouble speaking, thinking, remembering things, paying attention, or understanding things
- problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms
- numbness and tingling (feeling like “pins and needles”)
- burning, throbbing, or stabbing pain
- changes in your handwriting

Please see additional Important Safety Information on pages 16-18. Please see full [Prescribing Information](#), including **BOXED WARNING**, and [Medication Guide](#).



Table of Contents

ELREXFIO Dosing.....	4-5
ELREXFIO Side Effects	6-9
Support From Pfizer to Help You During Treatment	10-11
Questions for Your Healthcare Provider	12-13
Tracking Your Treatment.....	14-15
Important Safety Information.....	16-18



ELREXFIO Dosing

ELREXFIO is a **ready-to-use treatment**, which means it doesn't require a special manufacturing process.

You will begin ELREXFIO on a "step-up" dosing schedule that typically takes place over the course of 8 days. The first 2 doses of ELREXFIO are called "step-up" doses. Then, you will receive your first treatment dose. This helps your body's immune system adjust to ELREXFIO by building up to a full dose.

- "Step-up" dose 1 is usually given on day 1 of treatment
- For "step-up" dose 2, your dose of ELREXFIO will be increased, and it is usually given on day 4 of treatment
- You should be hospitalized while receiving the first 2 doses due to the risk of CRS, for 48 hours after dose 1, and 24 hours after dose 2
- Your ELREXFIO dose will be increased again when you receive the first treatment dose, which is usually given on day 8 of treatment

After completing the "step-up" dosing schedule, you will likely begin once a week treatment with ELREXFIO at your healthcare provider's office or another outpatient setting. After taking ELREXFIO for 6 months, your healthcare provider will assess how you are doing on treatment and decide if an every other week dosing schedule could be right for you.

Premedication: Before your first 3 doses of ELREXFIO, your healthcare provider will give you other medications to help reduce your risk of CRS, a serious side effect.

— "Step-up" dosing schedule —

Doses with hospitalization

Doses with premedication

1 st "step-up" dose Day 1	2 nd "step-up" dose Day 4	3 rd dose Day 8 (first treatment dose)	Weekly dosing Weeks 3-24 (starting on day 15)	Every other week dosing Week 25+
--	--	--	--	---

- ELREXFIO will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in your stomach area (abdomen). Your thigh or another area of your body may also be used
- After 6 months of treatment, your healthcare provider will evaluate your progress and decide if an every other week dosing schedule could be right for you



Please see Important Safety Information on pages 16-18. Please see full Prescribing Information, including **BOXED WARNING**, and Medication Guide.

Possible Side Effects With ELREXFIO

It's important to be aware of potential side effects while on ELREXFIO. Most who had side effects during treatment with ELREXFIO were able to manage them and continue on treatment.

ELREXFIO may cause serious, life-threatening side effects. These include **cytokine release syndrome (CRS)** and **neurologic problems**.

CRS is a result of the immune system becoming overactive. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, including:

- Fever of 100.4°F (38°C) or higher
- Trouble breathing
- Chills
- Dizziness or light-headedness
- Fast heartbeat
- Headache
- Increased liver enzymes in your blood

CRS is common during treatment with ELREXFIO and can also be serious, life-threatening, or can lead to death.

In a clinical trial, 58% of people taking ELREXFIO had CRS. The majority of CRS events were low-grade. Most happened early and were resolved with proper treatment.

Neurologic problems are potential serious side effects of ELREXFIO. In a clinical trial, 59% of people taking ELREXFIO experienced neurologic problems. 7% of people experienced severe neurologic problems (occurrences that were Grade 3 or 4).

Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of neurologic problems, including:

- Headache
- Agitation, trouble staying awake, confusion or disorientation, or seeing or hearing things that are not real (hallucinations)
- Trouble speaking, thinking, remembering things, paying attention, or understanding things
- Problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms
- Numbness and tingling (feeling like "pins and needles")
- Burning, throbbing, or stabbing pain
- Changes in your handwriting

ELREXFIO Risk Evaluation and Mitigation Strategy (REMS) Program

The Food and Drug Administration (FDA) requires a drug safety program for ELREXFIO due to the risk of CRS and neurologic problems. This drug safety program, called a Risk Evaluation and Mitigation Strategy (REMS) Program, requires healthcare professionals to be aware of and monitor the serious side effects that can happen when taking ELREXFIO.

As part of the ELREXFIO REMS Program, your healthcare provider will give you an ELREXFIO Patient Wallet Card before or at your first ELREXFIO treatment. It will let your other healthcare providers know that you have been prescribed ELREXFIO and includes symptoms of CRS or neurologic problems to look out for in case you experience them. **Get medical help right away if you develop any of the symptoms listed on the ELREXFIO Patient Wallet Card.** You may need to be treated in a hospital. **Be sure to carry your ELREXFIO Patient Wallet Card with you at all times and show it to all of your healthcare providers.**



Other Side Effects of ELREXFIO

Some other side effects of ELREXFIO may include:

Infections: Upper respiratory tract infection and pneumonia are common during treatment with ELREXFIO. ELREXFIO can cause bacterial and viral infections that are severe, life-threatening, or that may lead to death.

In people who received ELREXFIO according to the recommended dosing schedule, serious infections, including opportunistic infections, occurred in 42% of people, Grade 3 or 4 infections were seen in 31% of people, and fatal infections in 7% of people. People with active infections should not start ELREXFIO.

Most infections responded to treatment. In a clinical trial, 6.5% of people with an infection had to permanently stop treatment with ELREXFIO. Your healthcare provider may prescribe treatments to help prevent some infections while on ELREXFIO.

Decreased white blood cell counts: Decreased white blood cell counts are common with ELREXFIO and can also be severe. A fever can occur with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will treat you as needed.

Liver problems: ELREXFIO can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Tell your healthcare provider if you develop any of the following signs or symptoms of liver problems:

- Tiredness
- Loss of appetite
- Pain in your right upper stomach-area (abdomen)
- Dark urine
- Yellowing of your skin or the white part of your eyes

Your healthcare provider will check your blood and monitor you for signs and symptoms of these serious side effects before you start and during treatment with ELREXFIO and may temporarily or completely stop treatment with ELREXFIO if you develop certain side effects.

In addition to the serious side effects, ELREXFIO can cause other side effects. The most common side effects of ELREXFIO include:

- Tiredness
- Injection site reaction, such as redness, itching, pain, bruising, rash, swelling, and tenderness
- Diarrhea
- Muscle and bone pain
- Decreased appetite
- Rash
- Cough
- Nausea
- Fever

The most common severe abnormal lab test results with ELREXFIO include decreased white blood cells, red blood cells, and platelets.

In a clinical trial, most people who had side effects during treatment with ELREXFIO were able to manage them and stay on treatment.



Support From Pfizer to Help You During Treatment

If you've been prescribed ELREXFIO, you can receive one-on-one support from a Pfizer Patient Access Navigator during your treatment. When you enroll in Pfizer Oncology Together™, be sure to opt in for Patient Access Navigator support. You will be assigned a Patient Access Navigator who will work directly with you and your care team to provide:

- **Access and financial assistance for eligible patients:** Patient Access Navigators can help you navigate your insurance coverage, including letting you and your care team know how much of your treatment is covered by insurance and what your out-of-pocket costs may be
 - If you need financial assistance to help you pay for your medicine, they can help identify potential resources for patients with commercial insurance, Medicare/ government insurance, or those who don't have insurance
- **Treatment coordination:** Your Patient Access Navigator can confirm your hospital discharge plan with you and your care team and provide you with the information you need to receive treatment at your healthcare provider's office
- **Support during your treatment*:** Patient Access Navigators can coordinate with you to confirm logistics, provide appointment reminders, and follow up on insurance needs

*Patient Access Navigators will provide support to patients through their first 6 months of ELREXFIO treatment.

For Patient Access Navigator support, visit PfizerOncologyTogether.com/PAN or call [1-877-744-5671](tel:1-877-744-5671) (Monday–Friday 8 AM–8 PM ET) to learn more.

Financial assistance

If needed, Pfizer Oncology Together can help you find financial assistance options for your prescribed ELREXFIO, including a co-pay savings program for eligible, commercially insured patients. [Limits, terms, and conditions apply.](#)



Please see Important Safety Information on pages 16-18. Please see full Prescribing Information, including BOXED WARNING, and Medication Guide.

ELREXFIO™
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 4.4 mg/1.1 mL | 76 mg/1.9 mL

Questions for Your Healthcare Provider

Below are some questions to consider asking your healthcare provider to better understand what to expect during ELREXFIO treatment.

Where will I receive my "step-up" doses of ELREXFIO during my first week of treatment?

What are the possible side effects that can occur with ELREXFIO, and what can I do to help manage them?

Where and when will I receive my ongoing doses?

How long can potential side effects last after receiving ELREXFIO?

How long will my appointments last when I'm getting my ELREXFIO treatment?

Are there any changes I need to make to my diet while receiving ELREXFIO? What about other medications, vitamins, or supplements?

Tracking Your Treatment

Use this chart to track your treatment while receiving ELREXFIO. Be sure to include information like how you're feeling after each dose and any direction from your healthcare provider.

Date:	How you're feeling:	Notes:

Date:	How you're feeling:	Notes:

Important Safety Information

ELREXFIO may cause side effects that are serious, life-threatening, or can lead to death, including cytokine release syndrome (CRS) and neurologic problems. CRS is common during treatment with ELREXFIO.

Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS or neurologic problems, including:

- fever of 100.4°F (38°C) or higher
- trouble breathing
- chills
- dizziness or light-headedness
- fast heartbeat
- headache
- increased liver enzymes in your blood
- agitation, trouble staying awake, confusion or disorientation, or seeing or hearing things that are not real (hallucinations)
- trouble speaking, thinking, remembering things, paying attention, or understanding things
- problems walking, muscle weakness, shaking (tremors), loss of balance, or muscle spasms
- numbness and tingling (feeling like “pins and needles”)
- burning, throbbing, or stabbing pain
- changes in your handwriting

Due to the risk of CRS, you will receive ELREXFIO on a “step-up” dosing schedule and should be hospitalized for 48 hours after the first “step-up” dose and for 24 hours after the second “step-up” dose of ELREXFIO.

- For your first dose, you will receive a smaller “step-up” dose of ELREXFIO on day 1
- For your second dose, you will receive a larger “step-up” dose of ELREXFIO, which is usually given on day 4 of treatment
- For your third dose, you will receive the first full “treatment” dose of ELREXFIO, which is usually given on day 8

If your dose of ELREXFIO is delayed for any reason, you may need to repeat step-up dosing. Before each dose of ELREXFIO you receive during the step-up dosing schedule, you will receive medicines to help reduce your risk of CRS. Your healthcare provider will decide if you need to receive medicines to help reduce your risk of CRS with future doses.

ELREXFIO is available only through the ELREXFIO Risk Evaluation and Mitigation Strategy (REMS) Program due to the risk of CRS and neurologic problems. You will receive an ELREXFIO Patient Wallet Card from your healthcare provider. **Carry the ELREXFIO Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The ELREXFIO Patient Wallet Card lists signs and symptoms of CRS and neurologic problems. **Get medical help right away if you develop any of the symptoms listed on the ELREXFIO Patient Wallet Card.** You may need to be treated in a hospital.

Before taking ELREXFIO, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. ELREXFIO may harm your unborn baby. **Females who are able to become pregnant** should have a pregnancy test before starting treatment with ELREXFIO and should use effective birth control during treatment and for 4 months after the last dose of ELREXFIO. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with ELREXFIO
- are breastfeeding or plan to breastfeed. It is not known if ELREXFIO passes into your breast milk. Do not breastfeed during treatment and for 4 months after your last dose of ELREXFIO

Tell your healthcare provider about all of the medications you take, including prescription and over-the-counter medications, vitamins, and herbal supplements.

Do not drive, operate heavy or potentially dangerous machinery, or do other dangerous activities during treatment with ELREXFIO:

- for 48 hours after completing each of the 2 doses of ELREXFIO that are part of the “step-up dosing schedule” and your first full treatment dose, **and**
- at any time during treatment with ELREXFIO if you develop any new neurologic symptoms, such as dizziness, confusion, shaking (tremors), sleepiness, or any other symptom that impairs consciousness, until the symptoms go away

Infections: Upper respiratory tract infection and pneumonia are common during treatment with ELREXFIO. ELREXFIO can cause bacterial and viral infections that are severe, life-threatening, or that may lead to death.

- Your healthcare provider may prescribe medications for you to help prevent infections and treat you as needed if you develop an infection during treatment with ELREXFIO
- Tell your healthcare provider right away if you develop any signs or symptoms of an infection during treatment with ELREXFIO, including: fever of 100.4°F (38°C) or higher, chills, cough, shortness of breath, chest pain, sore throat, pain during urination, or feeling weak or generally unwell
- People with active infections should not start ELREXFIO

Decreased white blood cell counts: Decreased white blood cell counts are common during treatment with ELREXFIO and can also be severe. A fever can occur with low white blood cell counts and may be a sign that you have an infection. Your healthcare provider will treat you as needed.

Please see full [Prescribing Information](#), including **BOXED WARNING**, and [Medication Guide](#).

Important Safety Information (continued)

Liver problems: ELREXFIO can cause increased liver enzymes and bilirubin in your blood. These increases can happen with or without you also having CRS. Tell your healthcare provider if you develop any signs of a liver problem, including:

- tiredness
- loss of appetite
- pain in your right upper stomach-area
- dark urine
- yellowing of your skin or the white part of your eyes

The most common side effects of ELREXFIO include:

- tiredness
- injection site reaction, such as redness, itching, pain, bruising, rash, swelling, and tenderness
- diarrhea
- muscle and bone pain
- decreased appetite
- rash
- cough
- nausea
- fever

The most common severe abnormal lab test results with ELREXFIO include decreased white blood cells, red blood cells, and platelets.

Your healthcare provider may temporarily or permanently stop ELREXFIO if you have any of the side effects listed and they are severe. These are not all of the possible side effects of ELREXFIO.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at [1-800-FDA-1088](https://www.fda.gov/medwatch).

What is ELREXFIO?

ELREXFIO is a prescription medication used to treat adults with multiple myeloma who:

- have already received at least 4 treatment regimens, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody to treat their multiple myeloma, **and**
- their cancer has come back or did not respond to prior treatment

ELREXFIO was approved based on patient responses and durability of response. There are ongoing studies to confirm its clinical benefit. It is not known if ELREXFIO is safe and effective in children.



Please see full [Prescribing Information](#), including **BOXED WARNING**, and [Medication Guide](#).

ELREXFIO™
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL | 76 mg/1.9 mL

Visit [ELREXFIO.com](https://www.ELREXFIO.com) to learn more
and get additional resources.



 **ELREXFIO™**
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL
76 mg/1.9 mL



© 2023 Pfizer Inc. All rights reserved.
December 2023. PP-E1A-USA-0305

Please see full [Prescribing Information](#), including **BOXED WARNING**, and [Medication Guide](#).