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

FDA-REQUIRED REMS SAFETY INFORMATION

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- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with ELREXFIO
- Required REMS Certification to prescribe ELREXFIO

Dear Healthcare Provider:

The purpose of this letter is to inform you of important safety information for ELREXFIO based on current prescribing information. The FDA has required this safety notice as part of the ELREXFIO REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity including ICANS.

Serious Risks of ELREXFIO

- **Cytokine release syndrome (CRS)**, including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO.
- Initiate treatment with the ELREXFIO step-up dosing schedule to reduce the risk of CRS.
- **Neurologic toxicity including ICANS** and serious and life-threatening reactions, can occur in patients receiving ELREXFIO.
- Monitor patients for signs or symptoms of neurologic toxicity including ICANS during treatment.
- Withhold ELREXFIO until CRS or neurologic toxicity including ICANS resolves or permanently discontinue ELREXFIO based on severity.

Enclosed for your review and awareness of these serious risks is the ELREXFIO **REMS Fact Sheet**, a non-promotional educational document reviewed by the FDA. The ELREXFIO **REMS Fact Sheet** will provide you with more detailed information about these serious risks and the ELREXFIO REMS requirements.

REMS Requirements

- Those who prescribe and/or dispense ELREXFIO must be aware of how to manage the risks of CRS and neurologic toxicity including ICANS.
- ELREXFIO is ONLY prescribed and/or dispensed by certified prescribers, pharmacies, and healthcare settings.
- Prescribers must counsel patients on signs and symptoms of CRS and neurologic toxicity including ICANS.
- Prescribers must complete and provide patients or their caregivers with the **Patient Wallet Card** before treatment initiation (first step-up dose).

Prescriber Knowledge, Attitude, and Behavior (KAB) Survey

The Prescriber KAB Survey is a part of the REMS commitment made by Pfizer Inc., to the FDA to help assess stakeholder knowledge as it pertains to the risks associated with the use of ELREXFIO and in determining if the ELREXFIO REMS is meeting its goal.

We ask that you consider participating in this voluntary KAB survey upon receipt of the survey invitation. The timetable in completing this Prescriber KAB Survey will be on or about the following time periods:

Survey Intervals	Survey Period
Year 1 Prescriber KAB Survey	April 4, 2024 - June 14, 2024
Year 2 Prescriber KAB Survey	April 4, 2025 - June 14, 2025
Year 3 Prescriber KAB Survey	April 4, 2026 - June 14, 2026

Indication

ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Adverse Event Reporting

Healthcare Providers must report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS Coordinating Center at 1-844-923-7845.

Healthcare providers should report all other suspected adverse events to Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For a complete safety profile of ELREXFIO, please see the Prescribing Information included.

For additional details about the REMS, please visit www.ELREXFIOREMS.com or contact the ELREXFIO REMS Coordinating Center at 1-844-923-7845.

Sincerely,
Pfizer Inc.