ELREXFIO™ REMS Fact Sheet

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

FDA - REQUIRED REMS SAFETY INFORMATION

ELREXFIO REMS Overview

- The ELREXFIO **R**isk **E**valuation and **M**itigation **S**trategy (REMS) is a safety program that manages the risks of Cytokine Release Syndrome (CRS) and Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The ELREXFIO REMS is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.
- Healthcare providers, pharmacies, and healthcare settings that prescribe and/or dispense ELREXFIO must be specially certified and trained on how to manage the risks of CRS and neurologic toxicity including ICANS.
- Patients or their caregivers must receive the **Patient Wallet Card** before the first step-up dose of ELREXFIO.
- Wholesalers-distributors must ONLY distribute ELREXFIO to certified pharmacies and healthcare settings.

What Are the Risks?

- 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.

How Can Healthcare Providers Manage the Risks?

- Follow the ELREXFIO step-up dosing schedule as outlined in the **Prescriber Training Program**.
- Administer pretreatment medications approximately 1 hour before each dose in the step-up dosing schedule (step-up dose 1, step-up dose 2, and the first treatment dose) of ELREXFIO to reduce the risk of CRS as outlined in the **Prescriber Training Program**.
- Complete and provide patients or their caregivers with the **Patient Wallet Card** before treatment initiation (first step-up dose).
- Counsel patients about the risks of CRS and neurologic toxicity including ICANS and to seek medical attention should signs or symptoms of CRS and neurologic toxicity occur.
- Advise patients not to drive or operate heavy or potentially dangerous machinery for 48 hours after completing each of the 2 step-up doses and the first treatment dose within the ELREXFIO step-up dosing schedule and in the event of new onset of any neurological toxicity symptoms until symptoms resolve.
- Instruct patients that they should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.
- Monitor patients for signs or symptoms of CRS and of neurologic toxicity during treatment.
    - At the first sign of CRS, immediately evaluate the patient for hospitalization. Administer supportive therapy based on severity and consider further management per current practice guidelines.
    - At the first sign of neurologic toxicity including ICANS immediately evaluate the patient and provide supportive therapy based on severity.

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ELREXFIO REMS Overview (continued)

- Withhold ELREXFIO until CRS or neurologic toxicity including ICANS resolves or permanently discontinue ELREXFIO based on severity, as indicated in the Prescribing Information.
- For further details on recommended actions to be taken and treatment guidance for CRS and neurologic toxicity including ICANS refer to the **Prescriber Training Program** and **Adverse Reaction Management Guide.**

Key Requirements of the ELREXFIO REMS

Healthcare providers who prescribe ELREXFIO

Receive training on the REMS requirements at www.ELREXFIOREMS.com by using the **Prescriber Training Program** and the **Adverse Reaction Management Guide**.

Successfully complete the **Knowledge Assessment** and submit it to the REMS online.

Enroll in the REMS by completing and submitting the **Prescriber Enrollment Form** online to the REMS. Fax and e-mail options are also available.

If ELREXFIO will be dispensed and administered in the same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Instruct patients that they should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose. Monitor patients for signs and symptoms of CRS and neurologic toxicity including ICANS during treatment with ELREXFIO.

Pharmacies and Healthcare Settings that dispense ELREXFIO

Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements.

NOTE: Certified ELREXFIO Prescribers cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

Authorized Representative must be trained at www.ELREXFIOREMS.com using the **Pharmacy and Healthcare Setting Training Program**.

Authorized Representative must enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** online to the REMS. Fax and e-mail options are also available.

Pharmacies and Healthcare Settings must verify prescriber certification in the ELREXFIO REMS before dispensing ELREXFIO.

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Key Requirements of the ELREXFIO REMS (continued)

Patients

- Receive the **Patient Wallet Card** before treatment.
- Should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.

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 more information, to enroll in the ELREXFIO REMS, and for all REMS materials go to www.ELREXFIOREMS.com.

Pfizer