LYNOZYFIC™ (linvoseltamab-gcpt) Injection 5mg | 200mg

LYNOZYFIC REMS FACT SHEET

FDA – REQUIRED REMS SAFETY INFORMATION

LYNOZYFIC REMS Overview

- The LYNOZYFIC Risk Evaluation and Mitigation Strategy (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 LYNOZYFIC REMS is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.
- Healthcare providers and pharmacies and healthcare settings that prescribe and/or dispense LYNOZYFIC 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 treatment initiation (first step-up dose).
- Wholesalers and distributors must only distribute LYNOZYFIC to certified pharmacies and healthcare settings.

What Are the Risks?

- CRS, including serious or life-threatening reactions, can occur in patients receiving LYNOZYFIC.
  - Initiate treatment with LYNOZYFIC step-up dosing to reduce the risk of CRS.
  - Manage CRS, withhold LYNOZYFIC until CRS resolves, modify the next dose or permanently discontinue based on severity.
- Neurologic toxicity, including ICANS, including serious or life-threatening reactions, can occur in patients receiving LYNOZYFIC.
  - Monitor patients for signs or symptoms of neurologic toxicity, including ICANS during treatment.
  - Manage neurologic toxicity, including ICANS, withhold LYNOZYFIC until neurologic toxicity, including ICANS resolves, and modify the next dose or permanently discontinue based on severity.

How Can Healthcare Providers Manage the Risks?

- Follow the LYNOZYFIC step-up dosing schedule as outlined in the **Prescriber Training Program**.
- Administer pretreatment medications and initiate therapy according to LYNOZYFIC step-up dosing to reduce the risk of CRS as outlined in the **Prescriber Training Program.**
- Counsel patients and their caregivers to seek immediate medical attention should the patient have signs or symptoms of CRS or neurologic toxicity, including ICANS.
- Complete the **Patient Wallet Card** and provide patients or their caregivers with the **Patient Wallet Card** prior to treatment initiation (first step-up dose).
- Advise patients that they should be hospitalized for 24 hours after administration of the first and second step-up doses of LYNOZYFIC.
  - Pretreatment medications as described in Section 2.3 of the Prescribing Information should be administered until two full doses are tolerated without CRS.
- Advise patients to refrain from driving, or operating heavy or potentially dangerous machinery, for 48 hours after completion of each of the step-up doses and in the event of new onset of any neurological symptoms, until symptoms resolve.
- Monitor patients for signs and symptoms of CRS after infusion. At the first sign of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care. Withhold LYNOZYFIC until CRS resolves and modify the next dose or permanently discontinue LYNOZYFIC based on severity.
- Monitor patients for signs or symptoms of neurologic toxicity, including ICANS during treatment. At the first sign of neurologic toxicity, including ICANS immediately evaluate the patient; provide supportive therapy and consider further management per current practice guidelines. Withhold LYNOZYFIC until ICANS resolves and modify the next dose or permanently discontinue LYNOZYFIC based on severity.
- 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**.

Phone: 1-855-212-6391
www.Lynozyficrems.com
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LYNOZYFICREMS@ubc.com
REGENERON SCIENCE TO MEDICINE®

 Approval: 07/2025

Key Requirements of the LYNOZYFIC REMS

Healthcare providers who prescribe LYNOZYFIC

- Receive training on the REMS requirements at **www.Lynozyficrems.com** using the **Prescribing Training Program** and the **Adverse Reaction Management Guide**.
- Successfully complete and submit the **Knowledge Assessment** and enroll in the REMS by completing and submitting the **Prescriber Enrollment Form**.
- If LYNOZYFIC 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 24 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.

Pharmacies and Healthcare Settings that dispense LYNOZYFIC

- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy and healthcare setting.

  Note: Certified LYNOZYFIC prescribers cannot be designated as an Authorized Representative for a certified pharmacy and healthcare setting.
- Have the Authorized Representative review the **Pharmacy and Healthcare Setting Training Program**.
- Have the Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form**.
- Train all relevant staff involved in dispensing LYNOZYFIC on the REMS requirements using the **Pharmacy and Healthcare Setting Training Program**.
- Pharmacies and healthcare settings must verify prescriber certification in the LYNOZYFIC REMS before dispensing LYNOZYFIC.
  - Pharmacies and healthcare settings must obtain authorization to dispense (REMS Dispense Authorization [RDA]) for the first prescription written by each prescriber, for each patient, which verifies the prescriber is certified.
  - Subsequent prescriptions from the same prescriber, for the same patient, do not require obtaining an RDA, but pharmacies and healthcare settings can check the database of certified prescribers thereafter.

Patients who are prescribed LYNOZYFIC

- Receive counseling from the prescriber using the **Patient Wallet Card** before treatment initiation.
- Receive the **Patient Wallet Card** from the prescriber.
- Have the **Patient Wallet Card** with them at all times and inform other healthcare providers about treatment with LYNOZYFIC.

Adverse Event Reporting

Healthcare providers must report serious adverse events of CRS and neurologic toxicity, including ICANS to the LYNOZYFIC REMS at 1-855-212-6391.

Healthcare providers should also report all other suspected adverse events associated with LYNOZYFIC to Regeneron Pharmaceuticals, Inc. at 1-844-734-6643 or medical.information@regeneron.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For further information, to enroll in the LYNOZYFIC REMS, and for all REMS materials please visit **www.Lynozyficrems.com** or call 1-855-212-6391.

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