BLENREP
belantamab
mafodotin-blmf
for injection 100 mg

FDA-REQUIRED REMS* SAFETY INFORMATION

Subject:

- **Risk of Ocular Toxicity with BLENREP Treatment**
- **FDA Required BLENREP REMS**

Dear Healthcare Provider:

This letter is to inform you about the risk of ocular toxicity associated with BLENREP and the BLENREP REMS. BLENREP is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

The U.S. Food and Drug Administration (FDA) has determined a Risk Evaluation and Mitigation Strategy (REMS) is necessary to manage the risk of ocular toxicity. BLENREP is only available through a restricted program; the BLENREP REMS.

Risks of BLENREP:

- BLENREP can cause changes in the corneal epithelium resulting in changes in vision, including severe vision loss and corneal ulcer, and symptoms such as blurred vision and dry eyes.
- Ophthalmic exams must be performed at baseline, prior to each dose, and promptly for worsening symptoms.
- Dosage modifications or discontinuation of treatment may be needed to mitigate the risk of ocular toxicity.

REMS Requirements

- Prescribers of BLENREP must be certified in the BLENREP REMS in order to prescribe BLENREP.
- Additional details about the requirements of the BLENREP REMS are included in the Factsheet that is included with this letter.
- To enroll in the BLENREP REMS, visit www.BLENREPREMS.com.

For additional details about the REMS, visit www.BLENREPREMS.com or contact the BLENREP REMS at 1-855-209-9188.

The information in this letter is not intended as a complete description of the benefits and risks associated with the use of BLENREP. Please see accompanying Prescribing Information including Medication Guide.

Adverse Event Reporting

You are encouraged to report adverse reactions of BLENREP to GSK at 1-888-825-5249 and/or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Sincerely,
GlaxoSmithKline

BLM-LTR-200007
0002-0008-18
GSK Final (08/2020)

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BLENREP REMS Fact Sheet

BLENREP REMS Overview

What is the BLENREP REMS (Risk Evaluation and Mitigation Strategy)?

The BLENREP REMS is a safety program that manages the risk of ocular toxicity from BLENREP. The BLENREP REMS is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. The BLENREP REMS is a restricted distribution program.

Prescribers must be certified with the program by enrolling and completing training in the BLENREP REMS

Healthcare Settings must be certified with the program and verify that patients are authorized to receive BLENREP

Patients must be enrolled in the BLENREP REMS and comply with monitoring

Wholesalers and distributors must only distribute BLENREP to certified Healthcare Settings

What is the Risk?

- BLENREP caused changes in the corneal epithelium resulting in:
  - Changes in vision, including severe vision loss and corneal ulcer
  - Symptoms such as blurred vision and dry eyes

How can Prescribers Manage the Risk?

- Counsel patients receiving BLENREP about the risk of ocular toxicity and on the need for ophthalmic examinations (visual acuity and slit lamp) at baseline, prior to each dose, and promptly for worsening symptoms.
- Assess the patient's ocular health by consulting an eye care professional to complete visual acuity and slit lamp examinations using the *Eye Care Professional Consult Request Form* or equivalent
- Assess the ophthalmic exam results for corneal adverse reactions, which are based on both corneal examination findings and changes in best-corrected visual acuity (BCVA). Document these findings using the *Patient Status Form* prior to each dose in the REMS.
- Manage corneal adverse reactions per the *Prescribing Information* with dose reductions or withhold BLENREP until improvement and resume, or permanently discontinue, based on severity.

To enroll in the BLENREP REMS Program
call 1-855-209-9188
go to www.BLENREPREMS.com

MORE INFORMATION >>

What are the key requirements of the BLENREP REMS?

Prescribers

- Review the training: *BLENREP Prescribing Information, Program Overview,* and *Education Program for Prescribers*
- Complete the *Knowledge Assessment* and *Prescriber Enrollment Form*
- Submit the completed and signed *Knowledge Assessment* and *Prescriber Enrollment Form* at www.BLENREPREMS.com, or fax to 1-888-635-1044
- You will not be able to prescribe BLENREP without completing your certification in the BLENREP REMS

Healthcare Settings

- Designate an authorized representative to review the following: *BLENREP Prescribing Information, Program Overview* and *Education Program for Healthcare Settings*
- Complete the *Healthcare Setting Enrollment Form*
- Implement staff training and procedures to comply with the BLENREP REMS
- You will not be able to order BLENREP without completing your certification in the BLENREP REMS

Patient Responsibilities

- Prescribers: Using the *Patient Guide*, counsel patient on ocular adverse reaction risk and ophthalmic exam requirements
- Complete the *Patient Enrollment Form* and submit a copy online or via fax

Wholesalers-Distributors

- Establish processes and procedures to ensure that BLENREP is distributed only to certified Healthcare Settings
- Train all relevant staff involved in distribution of the BLENREP REMS requirements

Reporting Adverse Events

You are encouraged to report adverse reactions of BLENREP to GSK at 1-888-825-5249 and/or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This *Fact Sheet* does not contain the complete safety information for BLENREP. For complete safety information, please see the full *Prescribing Information*, including Boxed Warning, available at www.BLENREPREMS.com.

For More Information and to enroll in the BLENREP REMS Program call 1-855-209-9188
go to www.BLENREPREMS.com

BLM-LTR-200009
0002-0008-20
GSK Final (08/2020)

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