

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