BLENREP Risk Evaluation and Mitigation Strategy (REMS) Patient Guide

**Patients:** Your healthcare provider will go over this Patient Guide with you. It is important to ask your healthcare provider any questions you might have during treatment with BLENREP.

**Healthcare Providers:** Review this Patient Guide with your patient prior to initiating treatment with BLENREP.
Why am I receiving this Patient Guide?
Before you receive BLENREP, you must read and agree to all the instructions in the BLENREP Risk Evaluation and Mitigation Strategy (REMS). Before prescribing BLENREP, your healthcare provider will explain the BLENREP REMS to you and ask you to sign the Patient Enrollment Form.

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What is BLENREP?

BLENREP is a prescription medicine used to treat adults with multiple myeloma who:
- have received at least 4 prior medicines to treat multiple myeloma, and
- their cancer has come back or did not respond to prior treatment.

It is not known if BLENREP is safe and effective in children.

What is the BLENREP REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks. FDA must approve these steps as part of a REMS.

Why does BLENREP have a REMS?

BLENREP has a REMS because of the risk of eye problems. The BLENREP REMS educates patients and doctors about the risks associated with BLENREP. You must be enrolled in the BLENREP REMS to get BLENREP.

What is the most important information I should know about the eye problems with BLENREP?

- Eye problems are common with BLENREP.
- BLENREP can cause changes to the surface of your eye that can lead to:
  - dry eyes
  - blurred vision
  - worsening vision
  - severe vision loss
  - open sores on the cornea (corneal ulcer)
- Tell your healthcare provider if you have any vision changes or eye problems during treatment with BLENREP.
- Your healthcare provider will send you to see an eye specialist to check your eyes:
  - before starting treatment
  - prior to each dose of BLENREP
  - if you have worsening symptoms of eye problems
- Tell your healthcare provider if you have a history of vision or eye problems.
- Even if your vision seems fine, it is important that you get your eyes checked during treatment with BLENREP because some changes can happen without symptoms and may only be seen on an eye exam.
- Tell your healthcare provider if you notice any changes with your eyes.
- You should use preservative-free lubricant eye drops at least 4 times per day during treatment with BLENREP as instructed by your healthcare provider.
- You should use caution when driving or operating machinery as BLENREP may affect your vision.
- Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye specialist.

Eye problems are not the only side effect you should be aware of while on treatment with BLENREP. For more information, please see the Medication Guide for BLENREP or talk to your healthcare provider.
How is BLENREP given?

BLENREP will be given to you by your healthcare provider by intravenous infusion into your vein over approximately 30 minutes.

BLENREP is usually given every 3 weeks.

Your healthcare provider will decide how many treatments you need.

Your healthcare provider may decrease your dose, temporarily stop or completely stop treatment with BLENREP if you have serious side effects.

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

How do I enroll in the BLENREP REMS and what is required of me?

1. Your healthcare provider will go over this Patient Guide with you to ensure you understand:
   - The risk of eye problems while you are on treatment with BLENREP, which can cause changes to the surface of your eye that can lead to dry eyes, blurred vision, worsening vision, severe vision loss, and corneal ulcer.
   - The need to see an eye specialist to check your eyes:
     - before starting treatment with BLENREP
     - prior to each dose of BLENREP
     - if you have worsening symptoms of eye problems
   - The eye exam performed by the eye specialist will include a slit lamp exam and a visual acuity exam.

   Slit lamp exam
   The surface of the eye is examined to identify damaged cells or any changes to the surface of the eye.

   Visual acuity exam
   A chart is placed a distance from you, and you are asked to read the letters. A visual acuity score of 20/20 is considered normal vision.

   • Your healthcare provider will discuss the importance of using preservative-free lubricant eye drops (Page 5 in this document)

2. Your healthcare provider will help you complete and sign the Patient Enrollment Form to enroll you in the BLENREP REMS.
Where can I Get More Information on BLENREP?

Your healthcare provider will give you a BLENREP Medication Guide at the beginning of your treatment course. You can ask your pharmacist or healthcare provider for information about BLENREP that is written for healthcare professionals. You can also find additional information at www.BLENREPREMS.com or call the BLENREP REMS at 1-855-209-9188.

You are encouraged to report side effects of prescription drugs to the FDA. Visit MedWatch online at www.fda.gov/medwatch, or call 1-800-FDA-1088.

BLENREP Treatment Overview

Preservative-free lubricant eye drops
You should use eye drops at least 4 times a day starting with the first infusion and continuing until end of treatment

First dose
Baseline eye exam
including slit lamp and visual acuity prior to initial dose

Second dose
Eye exam prior to each dose

Third dose
Eye exam prior to each dose

Ongoing treatment
Eye exam prior to each dose

- Eye exams are required for treatment with BLENREP. Your doctor will use your eye exam results to make sure that you are receiving the correct dose.
- If you experience eye problems during treatment with BLENREP you may need to see your eye care specialist more often.

Slit lamp exam
The surface of the eye is examined to identify damaged cells or any changes to the surface of the eye.

Visual acuity exam
A chart is placed a distance from you, and you are asked to read the letters. A visual acuity score of 20/20 is considered normal vision.