

# **BLENREP** **Risk Evaluation and Mitigation Strategy (REMS)**

## **Patient Guide**

 **BLENREP**  
belantamab  
mafodotin-blmf  
for injection 70 mg

## **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.
  - You may want to keep this **Patient Guide** for future reference.
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## **Healthcare Providers:**

- Review this **Patient Guide** with your patient before initiating treatment with BLENREP.

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# Why am I receiving this Patient Guide?

This **Patient Guide** will give you information on the risk of eye problems with BLENREP. Before prescribing BLENREP, your healthcare provider will give you this **Patient Guide**. You will receive counseling on the risk of eye problems and the need for eye exams.

## What is BLENREP?

BLENREP is a prescription medicine used in combination with the medicines bortezomib and dexamethasone to treat adults with multiple myeloma who:

- Have received at least 2 prior treatment(s), including a proteasome inhibitor and an immunomodulatory agent, 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 most important information I should know about the risk of eye problems during treatment with BLENREP?

**BLENREP can cause serious side effects including:**

- **Eye problems.** Eye problems are common with BLENREP and can also be severe. BLENREP can cause changes to the surface of your eye, which can lead to symptoms of eye problems, including:



Decreased vision



Blurred Vision



Dry eyes



Sensitivity to light



Feeling like something is in your eyes



Eye irritation



Eye pain

Ulcers on the surface of the eye (corneal ulcers), including with infection, may also happen during treatment with BLENREP.

**Tell your healthcare provider right away** if you notice any new or worsening eye symptoms or vision changes during treatment with BLENREP.

# How can I manage the risk of eye problems with BLENREP?

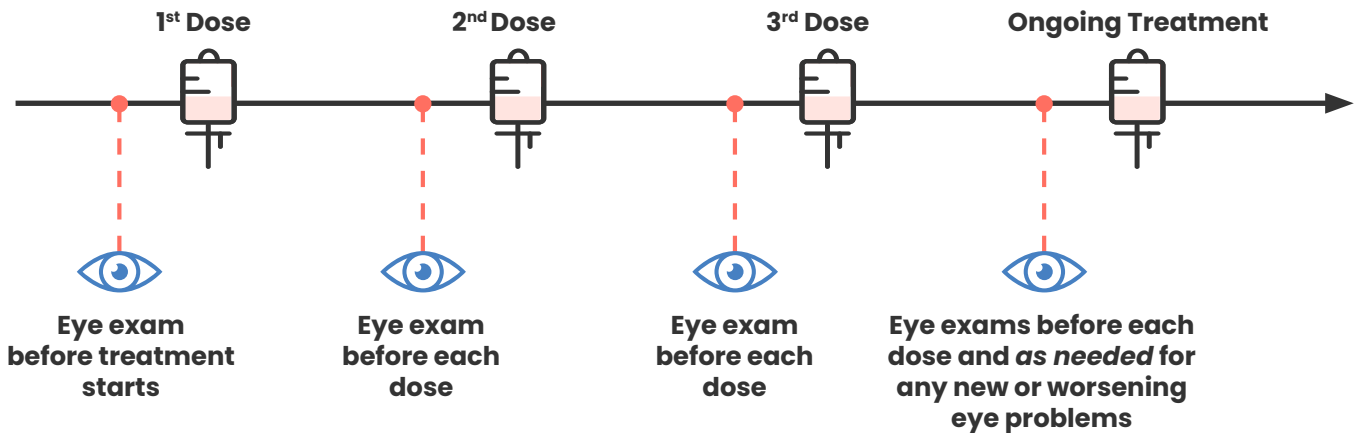
Your healthcare provider will refer you to an eye care specialist (such as an ophthalmologist or optometrist) to check your eyes before you start treatment, before you receive each dose of BLENREP, and as needed for any new or worsening eye problems. **It is important that you:**

- Keep all of your eye care appointments because some changes can happen without symptoms and may only be seen on an eye exam.
- Use preservative-free artificial tears at least 4 times per day starting with your first infusion and continuing until the end of treatment with BLENREP.
- Avoid wearing contact lenses during treatment with BLENREP unless directed by your eye care specialist.
- Use caution when driving or operating machinery because BLENREP may cause changes to your vision.

**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.**

# When do I need to get eye exams?

- Eye exams are required before treatment starts, before each dose, and as needed for any new or worsening eye problems (see below).



## What are preservative-free artificial tears? How often do I use them and why?

- Preservative-free artificial tears are an over-the-counter eye drop medicine used to lubricate dry eyes and help keep moisture on your eyes. Preservative-free artificial tears may come in single-dose vials.
- Use preservative-free artificial tears at least 4 times per day starting with the first infusion and continuing until the end of BLENREP treatment.
- Artificial tears with preservatives are not recommended as they may irritate your eyes, especially if you have dry eyes.

# How will I receive BLENREP?



Your healthcare provider will give you BLENREP as an infusion into your vein over about 30 minutes.



BLENREP is usually given every 3 weeks.



Your healthcare provider will decide how many treatments you will need.



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

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

**Because of the risk of eye problems, BLENREP is available only through a restricted program called the BLENREP REMS.**

Your healthcare provider will give you the BLENREP REMS **Patient Guide**, which describes the risk of eye problems, and will explain the REMS program to you. To receive BLENREP, you must enroll in the REMS program and receive eye exams during treatment.

## How do I enroll in the BLENREP REMS? What is required of me?

1. Review the **Patient Guide**.
2. Your healthcare provider will go over this **Patient Guide** with you to ensure you understand:
  - The risk of eye problems during treatment with BLENREP.
  - The need to see an eye care specialist to check your eyes:
    - Before treatment starts,
    - Before each dose, and
    - As needed for any new or worsening eye problems.
3. Complete the **Patient Enrollment Form**. Your healthcare provider will help you with this.

## Where can I get more information on BLENREP?

Your healthcare provider will give you a BLENREP Medication Guide at the beginning of your treatment. You can ask your pharmacist or healthcare provider for information about BLENREP that is written for health professionals.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Notes:

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US-BLM-LTR-250004  
0002-0037-32  
REMS-102025

