# BLENREP: Dosage and Administration Guide

BLENREP
belantamab mafodotin-blmf
for injection 70 mg

## INDICATION

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

## IMPORTANT SAFETY INFORMATION

**WARNING: OCULAR TOXICITY**

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

**Please see Important Safety Information continued throughout and click to see full Prescribing Information, including Boxed Warning for BLENREP.**

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## BLENREP is delivered by a ~30-minute outpatient infusion, at a REMS-certified site of their choice[1,2]

**BLENREP does not have a requirement for hospitalization to initiate treatment[2]**

**Systemic premedication** is not indicated for initial BLENREP dosing, but may be required to address infusion-related reactions[1]

BLENREP allows patients the **potential to avoid traveling far** for treatment[2]

**Ophthalmic exams** must be conducted by an eye care professional at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated.[1] Perform baseline exam within 4 weeks prior to the first dose. Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible.

- Advise patients to use preservative-free artificial tears at least 4 times per day and to avoid contact lenses during treatment with BLENREP unless directed otherwise by their eye care professional[1]

## BLENREP dosage overview[1]

**RECOMMENDED BLENREP STARTING DOSAGE**

2.5 mg/kg on day 1 of cycles 1-8 (Q3W) (21-day cycles)

**BLENREP + bortezomib + dexamethasone**

**CONTINUE BLENREP AS A SINGLE AGENT**

2.5 mg/kg (Q3W)

until disease progression or unacceptable toxicity

**Reduced Dosage:**

- Level 1: 1.9 mg/kg every 3 weeks
- Level 2: 1.9 mg/kg every 8 weeks*

See full dosing and administration information in BLENREP Prescribing Information.

**87% of patients required a dosage modification** of BLENREP for an adverse reaction.[1]

*Reduced Dosage Level 2 is specific to dosage reductions due to ocular toxicity based on ophthalmic exam findings.[1]

Q3W=every 3 weeks.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

**Ocular Toxicity**

BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.



## Patients may experience ocular toxicity[1]

Ocular toxicity occurred in 92% of patients in DREAMM-7, including Grade 3 or 4 in 77% of patients

### What is ocular toxicity?

Ocular toxicity is defined as changes in the corneal epithelium and changes in Best-Corrected Visual Acuity (BCVA) based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.[1]

### Identifying the need for dosage modifications

Recommended dosage modifications are **based on ophthalmic exam findings,** which include both corneal exam findings and changes in BCVA as assessed by an eye care professional.[1]

### Exam findings

**The overall grade of ophthalmic exam findings is based on the worst finding in the worst affected eye**, based on either corneal exam findings or a change in BCVA. Corneal exam findings may or may not be accompanied by changes in BCVA or ocular symptoms.[1]

### Working with an eye care professional

**The eye care professional will conduct the eye exams** and communicate the grade of the worst finding to the healthcare provider, who should subsequently determine if dosage modifications are needed.[1]

### Dosage modifications for ocular adverse reactions based on ophthalmic exam findings[1]

- 83% of patients required a dosage modification of BLENREP for ocular toxicity based on ophthalmic exam findings or other ocular adverse reactions as defined by the CTCAE
- 67% of patients required a dosage interruption of BLENREP for ocular toxicity that lasted longer than 3 weeks (time between doses, median: 5.7 weeks [range: 3 to 31 weeks])

**Do not re-escalate the dose of BLENREP after a dosage reduction is made for ocular toxicity based on ophthalmic exam findings[1]**

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## Dosage modifications for ocular toxicity based on ophthalmic exam findings[1]

| Severity | Ophthalmic Exam Findings | Recommended Dosage Modification |
|---|---|---|
| **Grade 1** | *Corneal Exam Findings*:<br>Mild superficial punctate keratopathy*<br>**and/or**<br>*Change in BCVA*:<br>Decline from baseline of 1 line on Snellen Equivalent BCVA | **Continue treatment at current dosage.** |
| **Grade 2** | *Corneal Exam Findings*:<br>Moderate superficial punctate keratopathy, patchy microcyst-like deposits,† peripheral sub-epithelial haze, or a new peripheral stromal opacity<br>**and/or**<br>*Change in BCVA*:<br>Decline from baseline of 2 lines on Snellen Equivalent BCVA and not worse than 20/200 | **Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. Resume treatment at Reduced Dosage Level 1 as per Table 1 in the USPI.<br>If recurrent Grade 2 or 3 ocular toxicity is experienced, resume treatment at Reduced Dosage Level 2 as per Table 1 in the USPI.** |
| **Grade 3** | *Corneal Exam Findings*:<br>Severe superficial punctate keratopathy, diffuse microcyst-like deposits† involving the central cornea, central sub-epithelial haze, or a new central stromal opacity<br>**and/or**<br>*Change in BCVA*:<br>Decline from baseline of 3 or more lines on Snellen Equivalent BCVA and not worse than 20/200 | |
| **Grade 4** | *Corneal Exam Findings*:<br>Corneal epithelial defect or corneal ulcer, with or without infection<br>**and/or**<br>*Change in BCVA*:<br>Decline to Snellen Equivalent BCVA of worse than 20/200 | **Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less. For patients previously on 2.5 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 1 as per Table 1 in the USPI. For patients previously on 1.9 mg/kg every 3 weeks, resume treatment at Reduced Dosage Level 2 as per Table 1 in the USPI. If recurrent Grade 4 ocular toxicity is experienced, permanently discontinue BLENREP.** |

*Mild superficial keratopathy (documented worsening from baseline).[1] Refer to Table 3 in the USPI for recommended dosage modifications for other ocular adverse reactions.
†Microcyst-like deposits are considered at least a Grade 2 finding. Withhold BLENREP if any microcyst-like deposits are observed.[1]
BCVA=Best-Corrected Visual Acuity.

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## Dosage modifications for other adverse reactions[1]*

| Adverse Reaction | Severity | Recommended Dose Modification |
|---|---|---|
| **Thrombocytopenia** | **Platelet count between 25,000/mcL and 50,000/mcL *without* bleeding** | **For patients on 2.5 mg/kg, reduce to Reduced Dosage Level 1 as per Table 1 in the USPI.† For patients on 1.9 mg/kg, continue at same dosage.** |
| | **Platelet count between 25,000/mcL and 50,000/mcL *with* bleeding** | **Withhold BLENREP until bleeding resolves. For patients previously on 2.5 mg/kg, resume at Reduced Dosage Level 1 as per Table 1 in the USPI. For patients on 1.9 mg/kg, resume at same dosage.** |
| | **Platelet count less than 25,000/mcL** | **Withhold BLENREP until platelet count recovers to 25,000/mcL or higher. For patients previously on 2.5 mg/kg, resume at Reduced Dosage Level 1 as per Table 1 in the USPI. For patients on 1.9 mg/kg, resume at same dosage.** |
| **Infusion-related reactions** | **Grade 2** | **Interrupt infusion and provide supportive care. Once symptoms resolve to Grade 1 or less, resume infusion at 50% of the initial rate prior to the event. Consider premedication for subsequent infusions.** |
| | **Grade 3** | **Interrupt infusion and provide supportive care. Once symptoms resolve to Grade 1 or less, resume infusion at 50% of the initial rate prior to the event. Administer premedication for subsequent infusions.** |
| | **Grade 4** | **Permanently discontinue BLENREP. If anaphylactic or life-threatening infusion reaction, permanently discontinue the infusion and institute appropriate emergency care.** |
| **Other Adverse Reactions** | **Grade 3** | **Withhold BLENREP until adverse reaction improves to Grade 1 or less. For patients previously on 2.5 mg/kg, resume at Reduced Dosage Level 1 as per Table 1 in the USPI. For patients on 1.9 mg/kg, resume at same dosage.** |
| | **Grade 4** | **Consider permanent discontinuation of BLENREP. If continuing treatment, withhold BLENREP until adverse reaction improves to Grade 1 or less. For patients previously on 2.5 mg/kg, resume at Reduced Dosage Level 1 as per Table 1 in the USPI. For patients on 1.9 mg/kg, resume at same dosage.** |

*Adverse reactions were graded according to the Common Terminology Criteria for Adverse Events v5.0.[1]
†Consider reverting to previous dose, if appropriate once platelet count recovers to 50,000/mcL or higher.[1]
AR=adverse reaction; BCVA=Best-Corrected Visual Acuity; BVd=BLENREP (B) + bortezomib (V) + dexamethasone (d).

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# BLENREP is a hazardous drug.[1] Follow applicable special handling and disposal procedures.

Calculate the dose (mg), total volume (mL) of solution required, and the number of vials of BLENREP needed based on the patient's actual body weight. More than one vial may be needed for a full dose.[1]

## Reconstitution[1]

- Remove the vial(s) of BLENREP from the refrigerator and allow to stand for approximately 10 minutes to reach room temperature (68°F to 77°F [20°C to 25°C])
- Reconstitute each 70 mg vial of BLENREP with 1.4 mL of Sterile Water for Injection, USP, to obtain a final concentration of 50 mg/mL. Gently swirl the vial to aid dissolution. **Do not shake**
- If reconstituted solution is not used immediately, store in the original container refrigerated at 36°F to 46°F (2°C to 8°C) or at room temperature (68°F to 77°F [20°C to 25°C]) for up to 4 hours. Discard if not diluted within 4 hours. **Do not freeze**
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The reconstituted solution should be a clear to opalescent, colorless to yellow to brown liquid. Discard if extraneous particulate matter is observed

## Dilution[1]

- Withdraw the calculated volume of BLENREP from the appropriate number of vials and dilute in a 250 mL infusion bag of 0.9% Sodium Chloride Injection, USP, to a final concentration of 0.2 mg/mL to 2 mg/mL. The infusion bags must be made of polyvinylchloride (PVC) or polyolefin (PO)
- Mix the diluted solution by gentle inversion. **Do not shake**
- Discard any unused reconstituted solution of BLENREP left in the vial(s)
- If the diluted infusion solution is not used immediately, store refrigerated at 36°F to 46°F (2°C to 8°C) for up to 24 hours. **Do not freeze.** Once removed from refrigeration, administer the diluted infusion solution of BLENREP within 6 hours (including infusion time)
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The diluted infusion solution should be clear and colorless. Discard if particulate matter is observed

USP=United States Pharmacopeia.

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## Administration[1]

- If refrigerated, allow the diluted infusion solution to equilibrate to room temperature (68°F to 77°F [20°C to 25°C]) prior to administration. Diluted infusion solution may be kept at room temperature for no more than 6 hours (including infusion time)
- Administer by intravenous infusion over approximately 30 minutes using an infusion set made of PVC or PO
- Filtration of the diluted solution is not required; however, if the diluted solution is filtered, use a polyethersulfone (PES)-based filter (0.2 micron)
- Do not mix or administer BLENREP with other products. The product does not contain a preservative

## Storage[1]

- BLENREP (belantamab mafodotin-blmf) for injection is a sterile, preservative-free, white to yellow lyophilized powder for reconstitution and further dilution prior to intravenous use
- BLENREP is supplied in a carton containing one 70 mg single-dose vial with a rubber stopper (not made with natural rubber latex) and aluminum overseal with removable cap (NDC 0173-0913-01)
- Store vials refrigerated at 36°F to 46°F (2°C to 8°C)

NDC=National Drug Code.

## IMPORTANT SAFETY INFORMATION
### WARNINGS AND PRECAUTIONS (CONT'D)

**Ocular Toxicity (cont'd)**
In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

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## Product information

| | |
|---|---|
| **NDC** | 0173-0913-01 |
| **Description** | BLENREP (belantamab mafodotin-blmf) |
| **Strength/Form** | For injection: 70 mg of belantamab mafodotin-blmf as a white to yellow lyophilized powder for reconstitution and further dilution prior to intravenous use. |

## Specialty distributors who are authorized to sell BLENREP

**ASD Healthcare (Cencora)**

Customer service phone
1-800-746-6273

Fax
1-800-547-9413

Website
asdhealthcare.com

Email
asd.customerservice@asdhealthcare.com

**Cardinal Health Specialty Pharmaceutical Distribution**

Physician offices
1-877-453-3972

Hospitals
1-855-855-0708

Specialty pharmacy/alt care
1-866-677-4844

Fax
1-614-553-6301

Website
orderexpress.cardinalhealth.com
specialtyonline.cardinalhealth.com

Email
GMB-SPD-CSORDERENTRY@cardinalhealth.com

**McKesson Plasma & Biologics**

Customer service phone
1-877-625-2566

Fax
1-888-752-7626

Website
Connect.mckesson.com

Email
mpborders@mckesson.com

**McKesson Specialty**

Customer service phone
1-800-482-6700

Oncology
1-800-482-6700

Multispecialty
1-855-477-9800

Fax
1-888-637-2473

Oncology Fax
1-855-824-9489

Multispecialty Fax
1-800-800-5673

Website
Mckessonspecialtyhealth.com

Email
oncologycustomersupport@mckesson.com
mshcustomercare-mspl@mckesson.com

**Oncology Supply (Cencora)**

Customer service phone
1-800-633-7555

Fax
1-800-248-8205

Website
oncologysupply.com

Email
custserv@oncologysupply.com

**For additional information on BLENREP,**
please call 1-844-4GSK-ONC (1-844-447-5662)
Monday–Friday: 8 AM–8 PM ET

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## INDICATION

BLENREP is indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.

## IMPORTANT SAFETY INFORMATION

**WARNING: OCULAR TOXICITY**

- **BLENREP causes changes in the corneal epithelium resulting in changes in vision, including severe visual impairment, and symptoms such as blurred vision and dry eyes. In the clinical study, corneal ulcers, including cases with infection, also occurred.**
- **Conduct ophthalmic exams at baseline, before each dose, promptly for new or worsening symptoms, and as clinically indicated. In the clinical study, 83% of patients required a dosage modification due to ocular toxicity. Withhold BLENREP until improvement and resume or permanently discontinue, based on severity.**
- **Because of the risk of ocular toxicity, BLENREP is available only through a restricted program called the BLENREP Risk Evaluation and Mitigation Strategy (REMS).**

## WARNINGS AND PRECAUTIONS

**Ocular Toxicity**

BLENREP causes ocular toxicity, defined as changes in the corneal epithelium and changes in BCVA based on ophthalmic exam (including slit lamp exam), or other ocular adverse reactions as defined by the CTCAE.

In DREAMM-7, ocular toxicity occurred in 92% of patients, including Grade 3 or 4 in 77% of patients. The most common ocular toxicities (>25%) were reduction in BCVA (89%) and corneal exam findings (86%) based on ophthalmic exam findings, blurred vision (66%), dry eye (51%), photophobia (47%), foreign body sensation in eyes (44%), eye irritation (43%), and eye pain (33%).

Ocular toxicity based on ophthalmic exam findings was reported as Grade 2 in 9% of patients, Grade 3 in 56% of patients, and Grade 4 in 21% of patients. The median time to onset of the first Grade 2 to 4 ophthalmic exam findings was 43 days (range: 15 to 611 days). The median duration of all Grade 2 to 4 ophthalmic exam findings was 85 days (range: 5 to 813 days). Patients experienced a median of 3 episodes (range: 1 to 11 episodes) of ocular toxicity based on ophthalmic exam findings. Of the patients with Grade 2 to 4 ophthalmic exam findings, 42% had improvement of the last event to Grade 1 or better; 22% had resolution of the last event based on return to baseline or normal ophthalmic exam findings.

The most commonly reported corneal exam findings included superficial punctate keratopathy, microcyst-like deposits, epithelial changes, and haze. Cases of corneal ulcer, including cases with infection, have been reported and should be managed promptly by an eye care professional.

A reduction in BCVA to 20/50 or worse in at least one eye occurred in 69% of patients, including 29% who experienced a change in BCVA to 20/100 or worse, and 12% who experienced a change in BCVA to 20/200 or worse. Of the patients with reduced BCVA to 20/50 or worse in at least one eye, 61% had resolution of the last event to baseline or better. Of the patients with reduced BCVA to 20/100 or worse, 57% had resolution of the last event. Of the patients with reduced BCVA to 20/200 or worse, 48% had resolution of the last event.

Ophthalmic exams (including slit lamp exam and BCVA assessment) should be conducted by an eye care professional, such as an ophthalmologist or optometrist, at baseline, before each dose of BLENREP, promptly for new or worsening symptoms, and as clinically indicated. Perform baseline exam within 4 weeks prior to the first dose.

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## IMPORTANT SAFETY INFORMATION
### WARNINGS AND PRECAUTIONS (CONT'D)

**Ocular Toxicity (cont'd)**
Perform each follow-up exam within 10 days prior to the next planned dose. All effort should be made to schedule the exam as close to BLENREP dosing as possible. Withhold BLENREP until improvement in both corneal exam findings and change in BCVA to Grade 1 or less and resume at same or reduced dose or permanently discontinue based on severity.

Counsel patients to promptly inform their healthcare provider of any ocular symptoms. Counsel patients to use preservative-free artificial tears at least 4 times a day starting with the first infusion and continuing until the end of treatment, and to avoid wearing contact lenses for the duration of therapy. Bandage contact lenses may be used under the direction of an eye care professional.

Changes in visual acuity may be associated with difficulty for driving and reading. Counsel patients to use caution when driving or operating machinery.

**BLENREP Risk Evaluation and Mitigation Strategy (REMS)**
BLENREP is available only through a restricted program called the BLENREP REMS because of the risk of ocular toxicity.

Further information is available at www.BLENREPREMS.com and 1-855-690-9572.

**Thrombocytopenia**
Thrombocytopenia of any grade occurred in 100% of patients in DREAMM-7.

Grade 2 thrombocytopenia occurred in 10% of patients, Grade 3 in 29% of patients, and Grade 4 in 45% of patients. Clinically significant bleeding (Grade ≥2) occurred in 7% of patients with concomitant low platelet levels (Grade 3 or 4).

Monitor complete blood cell counts at baseline and periodically during treatment as clinically indicated. Withhold or reduce the dose of BLENREP based on severity.

**Embryo-fetal Toxicity**
Based on its mechanism of action, BLENREP can cause fetal harm when administered to a pregnant woman because it contains a genotoxic compound (the microtubule inhibitor, monomethyl auristatin F [MMAF]) and it targets actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with BLENREP and for 4 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with BLENREP and for 6 months after the last dose.

## ADVERSE REACTIONS

The most common adverse reactions (≥20%) with BLENREP in combination with bortezomib and dexamethasone are reduction in BCVA, corneal exam findings, blurred vision, dry eye, photophobia, foreign body sensation in eyes, eye irritation, upper respiratory tract infection, hepatotoxicity, eye pain, diarrhea, fatigue, pneumonia, cataract and COVID-19.

The most common Grade 3 or 4 (≥10%) laboratory abnormalities are decreased platelets, decreased lymphocytes, decreased neutrophils, increased gamma-glutamyl transferase, decreased white blood cells, and decreased hemoglobin.

**Please see Important Safety Information continued throughout and click to see full Prescribing Information, including Boxed Warning for BLENREP.**



# References

**1.** BLENREP. Prescribing information. GSK; 2025. **2.** Hungria V, Robak P, Hus M, et al. Belantamab mafodotin, bortezomib, and dexamethasone for multiple myeloma. *N Engl J Med*. 2024;391(5):393-407. doi:10.1056/NEJMoa2405090

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**Support and resources are available for you and your patients being treated with BLENREP**

For more information visit **BLENREPhcp.com**.

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For US Healthcare Professionals Only.



GSK


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