Corneal adverse reactions may include findings upon eye examination and/or changes in visual acuity. The treating physician should review the patient's ophthalmic examination report before dosing and should determine the dose of BLENREP based on the highest category from the report in the most severely affected eye, as both eyes may not be affected to the same degree. During the ophthalmic examination, assess the following:

#### **Grading Scale for** Corneal Adverse **Reactions**<sup>1</sup>

**Dose Modifications** or Discontinuation May Be Required<sup>1</sup>

- The corneal examination finding(s) and the decline in best corrected visual acuity (BCVA)
- If there is a decline in BCVA, the relationship of corneal examination findings to BLENREP should be determined
- The highest category grading for these examination findings and BCVA should be reported to the treating physician

Patients should have an ophthalmic examination (including visual acuity and slit lamp examination) performed by an eye care professional at baseline, before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment.

Category <sup>a,b</sup>	Eye examination findings	Recommended dose modifications		
Mild	Corneal examination finding(s) Mild superficial keratopathy <sup>c</sup> Change in BCVA Decline from baseline of 1 line on Snellen Visual Acuity	• Continue treatment at current dose		
Moderate	Corneal examination finding(s) Moderate superficial keratopathy <sup>d</sup> Change in BCVA Decline from baseline of 2 or 3 lines (and Snellen Visual Acuity not worse than 20/200)	<ul> <li>Withhold treatment until improvement in examination findings and BCVA to mild severity or better</li> <li>Consider resuming treatment at a reduced dose of 1.9 mg/kg</li> </ul>		
Severe	Corneal examination finding(s) Severe superficial keratopathy <sup>e</sup> Corneal epithelial defect <sup>f</sup> Change in BCVA Decline from baseline of more than 3 lines	<ul> <li>Withhold until improvement in examination findings and BCVA to mild severity or better</li> <li>For worsening symptoms that are unresponsive to appropriate management, consider discontinuation</li> </ul>		

<sup>a</sup>Note: This guide does not cover all potential adverse reactions and recommended dose modifications.

<sup>b</sup>The severity category is defined by the most severely affected eye, as both eyes may not be affected to the same degree.

<sup>c</sup>Mild superficial keratopathy (documented worsening from baseline), with or without symptoms.

<sup>d</sup>Moderate superficial keratopathy—with or without patchy microcyst-like deposits, subepithelial haze (peripheral), or a new peripheral stromal opacity.

\*Severe superficial keratopathy with or without diffuse microcyst-like deposits involving the central cornea, subepithelial haze (central), or a new central stromal opacity.

fA corneal defect may lead to corneal ulcers. These should be managed promptly and as clinically indicated by an eye care professional.

Please consult your doctor for further information.

Your doctor will advise you on the most appropriate course of action.



# **Corneal Adverse Reactions Have Been Reported With** the Use of BLENREP<sup>1</sup>

- dry eye events (15%), photophobia (4%), and eye irritation (3%)

- including best corrected visual acuity (BCVA)
- 3% of patients discontinued treatment due to ocular events
- severe vision loss (20/200 or worse) in the better-seeing eye was reported in 1% of patients
- corneal ulcer has healed

#### Reference

1. BLENREP (belantamab mafodotin) Singapore Package Insert

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For further information, please consult your doctor or pharmacist. For reporting of adverse events please write to sg.drugsafety@gsk.com. All images used in this material are for illustration purposes only. © 2024 GSK group of companies or its licensor. GlaxoSmithKline Pte Ltd, 23 Rochester Park, Singapore 139234, registered in Singapore No. 198102938K Tel: +65 62328338 Fax: +65 62010737 NP-SG-BLM-LBND-220007. Date of Approval: September 2024.

• The reported eye disorder adverse reactions ( $\geq$ 3%) were keratopathy (71%), blurred vision events (25%),

• Keratopathy or microcyst-like epithelial changes was characterised as changes in corneal epithelium (as seen on eye examination) with or without changes in visual acuity, blurred vision, and dry eye symptoms

• Patients with a history of dry eyes were more prone to develop changes in the corneal epithelium

• Collection of corneal adverse events included patient-reported adverse reactions and ocular exam findings

• The median time to onset of Grade 2 or above corneal findings (BCVA or keratopathy on eye examination) was 36 days (range: 19 to 143 days), and the median time to resolution of these corneal findings was 91 days (range: 21 to 201 days)

• Corneal findings (keratopathy) led to dose delays in 47% of patients and dose reductions in 27% of patients.

• Decreased vision (Snellen Visual Acuity worse than 20/50) in the better eye was reported in 18% of patients and

• Cases of corneal ulcer (ulcerative and infective keratitis) have been reported. These should be managed promptly and as clinically indicated by an eye care professional. Treatment with BLENREP should be interrupted until the

Eye Care **Evaluation** Guide



This leaflet is to be kept in the doctor's consultation room and to be given only by doctors to patients who have been prescribed with BLENREP.

Please bring this leaflet to your next medical appointment.





## **Eye Care Evaluation Guide Overview/Instructions**

This guide is intended to cover important information related to corneal adverse reactions associated with BLENREP, adverse event management, and instructions to facilitate communication between prescribers and eye care professionals\* for patients prescribed BLENREP.

## PATIENT INFORMATION

Patient name:

Date of most recent or scheduled infusion:

Date of eye care professional appointment:

## HAEMATOLOGIST/ONCOLOGIST

- Complete your preferred contact information to receive exam results
- Provide this form to patients prescribed BLENREP
- Determine the dose of BLENREP based on recommended dose modifications on page 5<sup>1</sup>
- Consult an eye care professional if corneal adverse reactions occur<sup>1</sup>
- Instruct patients to complete the patient information section of this form
- Instruct patients to bring this form to every eye care professional visit to reinforce that ophthalmic exam results should be communicated between the eye care professional and haematologist/oncologist

#### HAEMATOLOGIST/ONCOLOGIST CONTACT INFORMATION

Name:	

Phone:

Fax:

Email:

## EYE CARE PROFESSIONAL

- Complete your preferred contact information so that the haematologist/oncologist can contact you if necessary
- Review the form for important information related to ophthalmic exams for patients taking BLENREP
- Return results to the haematologist/oncologist through secure fax, email, or preferred method to ensure the haematologist/oncologist can make informed decisions on potential dose modifications or discontinuation in consultation with you (see grading scale on page 5). Fill out new sections for each follow-up examination

Name:

Fax:

Email:

Phone:

\*Eye care professional refers to an ophthalmologist who is able to provide comprehensive eye care to the patient, including routine eye-check-ups and treatment and management of visual diseases.



# **Corneal Examination Findings and Best Corrected Visual Acuity**

Please refer to page 5 for information on relevant examination findings for BLENREP.

## **Section 1: For Baseline Examination Only**

Date of Assessment:

What are the current best corrected visual acuity results (Snellen Visual Acuity)? OS \_\_\_\_/ \_\_\_ OD \_\_\_\_/

Any pre-existing ocular conditions the prescriber should be aware of:

### Section 2: Ophthalmic Exam Before 2nd Dose

Date of Assessment:

What are the current best corrected visual acuity results (Snellen Visual Acuity)? OS \_\_\_\_/ OD \_\_\_\_/ Were there findings upon corneal examination and/or visual acuity assessment? Y / N If Y, please check affected eyes \_\_OS \_\_OD \_\_OU

Corneal Examination Findings and BCVA Changes From Baseline					
<b>Corneal Examination Findings</b>	Left Eye (OS)	Right Eye (OD)	BCVA Changes From Baseline (on Snellen Visual Acuity)	Left Eye (OS)	Right Eye (OD)
Check one			Check one		
Mild superficial keratopathy			No change from baseline		
Moderate superficial keratopathy			Decline from baseline of 1 line		
Severe superficial keratopathy			Decline from baseline of 2 or 3 lines		
Corneal epithelial defect			Decline from baseline of more than 3 lines		
Other					

OS=left eye; OD=right eye; OU=both eyes.



The recommended dose of **BLENREP** is 2.5 mg/kg administered as an intravenous (IV) infusion once every 3 WEEKS until disease progression or unacceptable toxicity<sup>1</sup>



Visual acuity and slit lamp exam should be performed by an eye care professional

Advise patients to:



## **MONITOR / MINIMISE / MODIFY** The 3 Ms of Corneal AE Management<sup>1</sup>



## **Ophthalmic Exam Before 1st Treatment**,

before the subsequent 3 treatment cycles, and as clinically indicated whilst on treatment



Administer preservative-free artificial tear drops at least 4 times a day beginning on the first day of infusion and continuing until completion of treatment, as this may reduce corneal symptoms

For patients with dry eye symptoms, additional therapies may be considered as recommended by their eye care professional

## **Corneal Examination Findings and Best Corrected Visual Acuity** (Continued)

#### Section 3: Ophthalmic Exam Before 3rd Dose

Date of Assessment:

What are the current best corrected visual acuity results (Snellen Visual Acuity)? OS \_\_\_ / \_\_\_ OD \_\_\_ / \_\_\_

Were there findings upon corneal examination and/or visual acuity assessment? Y / N

### If Y, please check affected eyes \_\_OS \_\_OD \_\_OU

Corneal Examination Findings and BCVA Changes From Baseline				
Corneal Examination Findings	Left Eye (OS)	Right Eye (OD)	BCVA Changes From Baseline (on Snellen Visual Acuity)	
Check one			Check one	Τ
Mild superficial keratopathy Moderate superficial keratopathy Severe superficial keratopathy Corneal epithelial defect			No change from baseline Decline from baseline of 1 line Decline from baseline of 2 or 3 lines Decline from baseline of more than 3 lines	
Other				

#### Section 4: Ophthalmic Exam Before 4th Dose

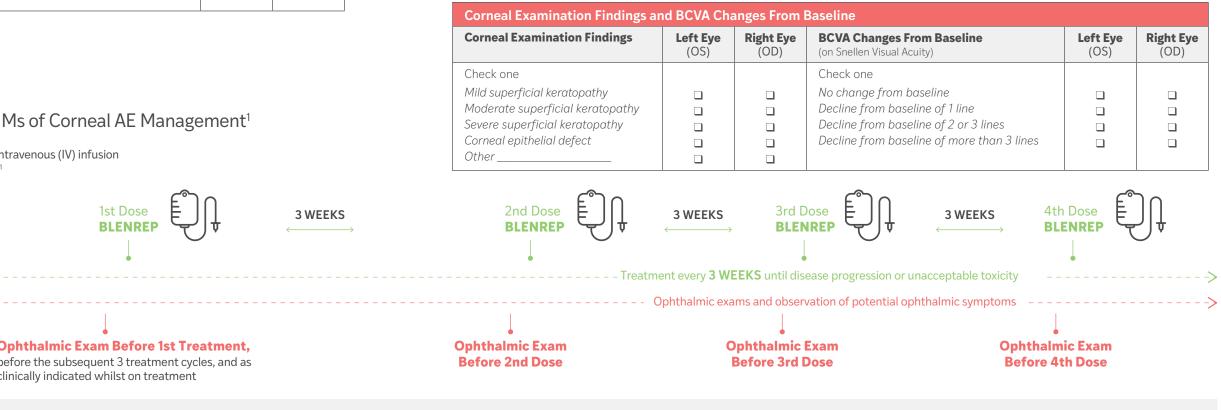
Date of Assessment:

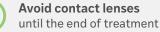
What are the current best corrected visual acuity results (Snellen Visual Acuity)? OS \_\_\_\_/ \_\_\_ OD \_\_\_\_/

Were there findings upon corneal examination and/or visual acuity assessment? Y / N

If Y, please check affected eyes \_\_OS \_\_OD \_\_OU

Corneal Examination Findings and BCVA Changes From Baseline					
<b>Corneal Examination Findings</b>	Left Eye (OS)	<b>Right Eye</b> (OD)	BCVA Changes From Baseline (on Snellen Visual Acuity)	L	
Check one			Check one		
Mild superficial keratopathy			No change from baseline		
Moderate superficial keratopathy			Decline from baseline of 1 line		
Severe superficial keratopathy			Decline from baseline of 2 or 3 lines		
Corneal epithelial defect			Decline from baseline of more than 3 lines		
Other					





Use caution when driving or operating machines

<b>Left Eye</b> (OS)	<b>Right Eye</b> (OD)



**Continue monitoring** for corneal adverse reactions after treatment and contact haematologist/oncologist if any symptoms occur