Patient Guide: Important Information on Understanding the Vision and Eye Changes That May Occur With BLENREP Treatment

This booklet 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.

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Introduction

This patient guide provides an overview of the vision and eye changes that may occur with BLENREP treatment and includes the following information for patients:

- A summary of the corneal adverse reactions that may occur with BLENREP
- What should patients do if they experience eye-related side effects
- A brief anatomy of the eye
- Signs and symptoms of vision and eye changes
- Frequently asked questions

Patients will receive this patient guide via their healthcare professional upon initiation of their treatment.

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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 and did not respond to prior treatment.

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

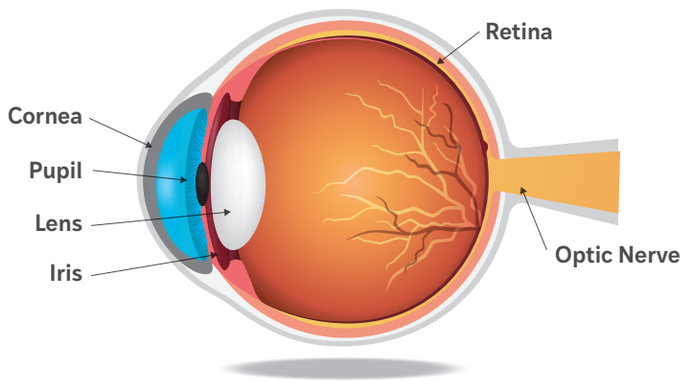
Monitoring Patients for Vision and Eye Changes with BLENREP Treatment

BLENREP has been associated with vision and eye changes as reported in clinical studies in patients with cancer. Because of this, you will be closely monitored for these types of changes during therapy. For information about possible non-ocular side effects of BLENREP, please refer to page 5 of this guide.

Understanding the Anatomy of the Eye and How It Relates to Possible Corneal Side Effects

In order to understand the changes to the vision and eye that have been reported with BLENREP, it's important to know the structures of the eye and how they work.

The eye is made up of many components that work together to help you see.



The cells in the outermost cornea layer are like your skin and they regrow, allowing for repair after injury

Anatomy of the eye. The cornea covers the iris and the pupil, and it helps focus most of the light that enters the eye.

The cornea, specifically the corneal surface, is the part of the eye that may have changes when you are being treated with BLENREP.

BLENREP can cause eye problems, including a disorder of the cornea of the eye called keratopathy that may only be seen on an eye examination.

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What to Expect During Treatment With BLENREP

The most commonly reported adverse reactions with BLENREP were changes to vision or eye problems (may affect more than 1 in 10 people) including:

- Disorder of the cornea of the eye (keratopathy).
- Blurred vision.
- Dry eyes.

Other eye problems that were considered common in patients receiving BLENREP (may affect up to 1 in 10 people) included:

- Sensitivity to light (photophobia).
- Eye irritation.

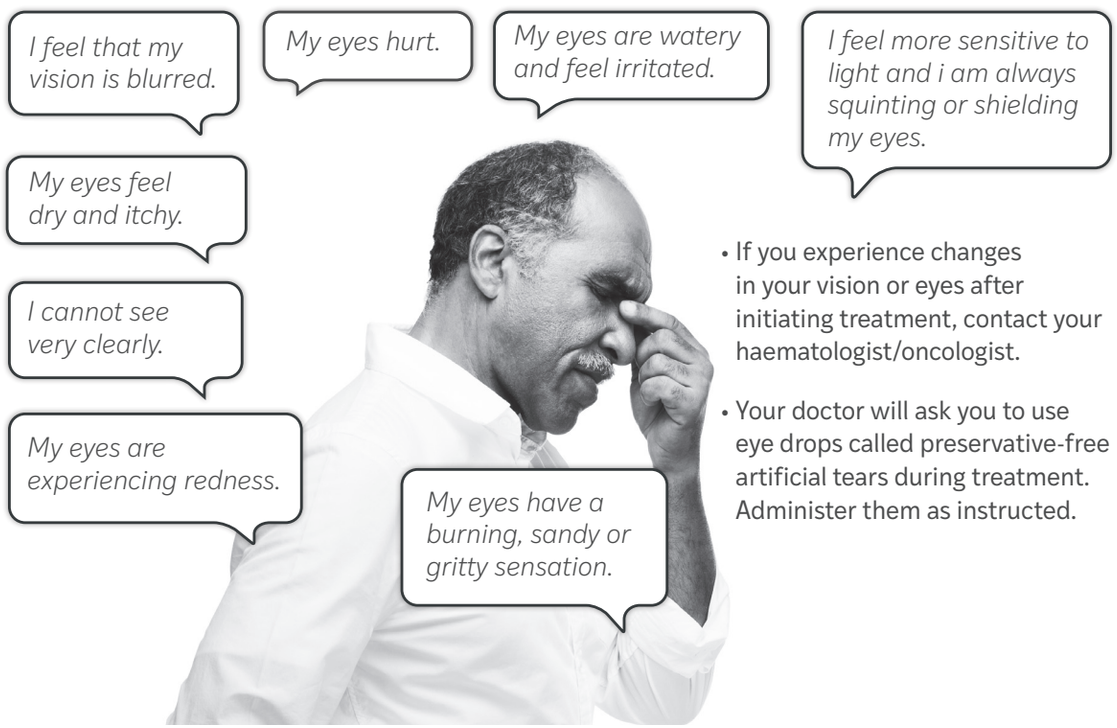
Uncommon eye problems in patients receiving BLENREP (may affect up to 1 in 100 people) included:

- Eye sores, possibly with infection (ulcerative and infective keratitis).

Instructions for Patients:

- Patients experiencing keratopathy with or without changes in visual acuity may require a dose modification (delay and/or reduction) or treatment discontinuation based on severity of findings.
- Tell your haematologist/oncologist about any history of vision or eye problems.

If you notice changes with your vision, your doctor may withhold treatment with BLENREP or adjust the dose or ask you to see an eye specialist. Symptoms include the following:



- If you experience changes in your vision or eyes after initiating treatment, contact your haematologist/oncologist.
- Your doctor will ask you to use eye drops called preservative-free artificial tears during treatment. Administer them as instructed.

Other side effects that occurred in more than 20% of people who received BLENREP are low platelets (38%), low red blood cell count (27%), nausea (25%), fever (23%), increased aspartate aminotransferase (21%), and infusion-related reactions (21%)

Platelets help your blood clot. A decrease in platelets can lead to abnormal bruising or bleeding.

Infusion-related reactions or allergic-like reactions can occur when you are receiving a BLENREP infusion. These usually develop within minutes or up to 24 hours after treatment.

These are not all the possible side effects of BLENREP.

If you experience any side effects while taking BLENREP, please contact your haematologist/oncologist.

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Eye-Related Side Effects:
MONITOR, MINIMISE, MODIFY

Your healthcare professionals should monitor and minimise any corneal symptoms you may experience and modify treatment as needed.

Eye examinations, including assessment of visual acuity and slit lamp examination, should be performed at baseline, before the subsequent 3 treatment cycles, and as clinically indicated while on treatment.

The recommended dose of **BLENREP** is 2.5 mg/kg administered as an intravenous infusion once every **3 WEEKS** until disease progression or unacceptable toxicity.

Be sure to:

- **Use 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
- **Avoid contact lenses** until the end of treatment
- **Use caution when driving or operating machines**
- **Continue monitoring** for corneal adverse reactions after treatment and contact your haematologist/oncologist if any symptoms occur

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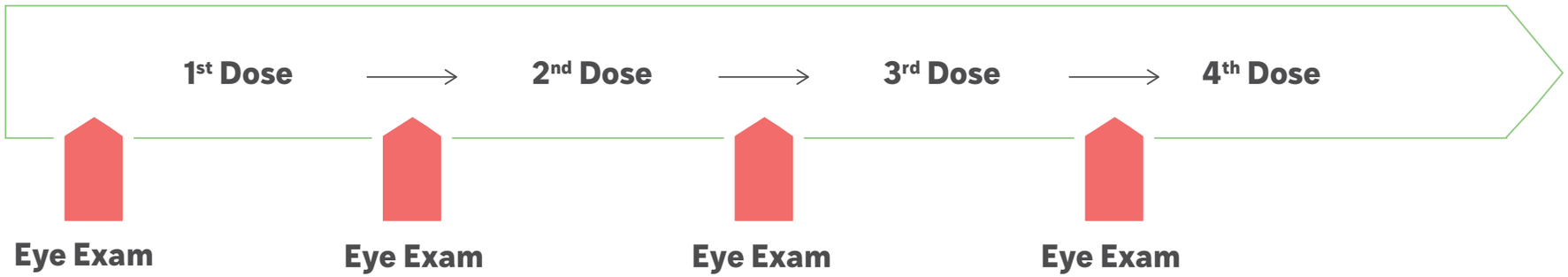
Treatment every **3 WEEKS** until disease progression or unacceptable toxicity



Eye exam before first treatment, before the next 3 treatment cycles, and as clinically indicated while on treatment

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

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Eye-Related Side Effects:
MONITOR, MINIMISE, MODIFY *(continued)*

MONITOR

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.

MINIMISE

Preservative-free artificial tears

There are many different lubricating eye drops (preservative-free artificial tears) available for purchase without a prescription. They are prescribed to lessen the effect of BLENREP on your eyes. Your healthcare professional will ask you to use these eye drops during treatment with BLENREP. Administer them as instructed.

MODIFY

Your dose of medication may need to be modified or changed

If you develop changes in vision or eyes that are moderate or severe, your haematologist/oncologist may decide to modify your therapy (lower your dose or withhold therapy until symptoms improve or resolve).

Signs and Symptoms of Vision and Eye Changes

Your eye care professional will monitor your vision before and during your treatment with BLENREP. You should also monitor for symptoms for yourself.

With normal vision, the image (or any external visual stimulus) will appear crisp without eye strain or irritation

Tell your haematologist/oncologist about any changes or decrease in vision, including any of the following symptoms:

Double vision

Blurred vision

Additional symptoms that you should tell your haematologist/oncologist about include:

- Dry eyes
- Eye irritation or pain
- Itchy eyes
- Sensitivity to light

Frequently Asked Questions

Q: What type of eye exams will I need before starting BLENREP, and when will these exams be conducted?

A: Eye exams, including visual acuity and slit lamp exams, should be performed by an eye care professional before starting treatment, before the subsequent 3 treatment cycles, and as clinically indicated while on treatment as directed by your doctor.

Q: Where do I get an eye exam?

A: An eye exam should be performed by an eye care professional. Your haematologist/oncologist office may provide a referral and schedule the appointment.

Q: What types of effects on my eyes may occur during and after treatment with BLENREP?

A: BLENREP can cause dry eyes, blurred vision, disorder of the cornea of the eye (keratopathy), sensitivity to light, and eye irritation. In the clinical trial, permanent loss of vision was not reported. 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 examination.

Q: When do vision and eye changes with BLENREP begin? How long do they last?

A: In the clinical trial, moderate to severe findings on the cornea were seen at approximately 36 days (range: 19 to 143 days) after starting BLENREP, and the time to resolution of these corneal findings was approximately 91 days (range: 21 to 201 days).

Q: Whom do I contact if the symptoms occur?

A: Consult your haematologist/oncologist. Your treatment with BLENREP may need to be modified.

Q: Are there any restrictions on certain daily activities involving vision after starting BLENREP?

A: You should avoid wearing contact lenses throughout treatment (which includes during infusion and in between infusions), unless you are directed to by an eye care professional. **Also, do not drive or use machines** unless you are sure your vision is not affected. Talk to your doctor if you are not sure.

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Frequently Asked Questions *(continued)*

Q: Why does BLENREP affect the eyes?

A: Though the exact reason is unknown, BLENREP is taken up into cells throughout the body, including cells on the surface of the cornea. BLENREP in these cells may lead to changes of the vision or eye.

Q: How can my vision and eye changes be managed?

A: Lubricating eye drops (preservative-free artificial tears) need to be administered at least 4 times a day, starting with the first infusion, and continuing until completion of treatment, as they may help minimise changes to the vision or eyes. If you have dry eye symptoms, additional therapies may be considered as recommended by your eye care professional. Your haematologist/oncologist may also need to reduce your dose of BLENREP.

Q: Will I have to stop treatment if there are adverse reactions that affect my eyes and/or vision?

A: Tell your haematologist/oncologist if vision and eye changes occur. A dose reduction of BLENREP may be recommended, or treatment may be withheld until symptoms improve. In cases where eye problems are severe, stopping treatment may be considered.

This material is produced as a service to patients by GlaxoSmithKline.
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For further information, please consult your doctor or pharmacist.
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