Changes in vision and eyes that may occur with BLENREP treatment

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Introduction

BLENREP is a medicine used to treat relapsed or refractory multiple myeloma in patients who have received at least 4 previous therapies, including an anti-CD38 monoclonal antibody (such as daratumumab), a proteasome inhibitor (such as Velcade/bortezomib), and an immunomodulatory agent (such as lenalidomide/ Revlimid).

BLENREP is the first medicine to be made of a conjugated antibody (an antibody connected to a substance that kills cancer cells) that targets an antigen (a type of protein) on mature B cells (BCMA). BCMA is a protein found on the surface of myeloma cells in all multiple myeloma patients. The linked medicine can enter myeloma cells and destroy them from inside and activate your immune system to fight the cancer.

An antibody is a defense protein produced by the immune system in response to a foreign substance. Sometimes antibodies can be produced in a laboratory and used to treat cancer. This linked antibody medicine can destroy cancer cells and stop them from dividing.

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Overview of BLENREP

BLENREP is the first treatment to target an antigen found on mature B cells and that is present on myeloma cells. It is possible that healthy cells will also be affected.

BLENREP is used to treat adult patients who have multiple myeloma. This cancer treatment is composed of two parts:

- a monoclonal antibody that attaches to multiple myeloma cells in the body
- an anti-cancer substance that kills the cancer cells

What is BLENREP and how does it work?

BLENREP works in three ways to help your body fight multiple myeloma. It activates three anti-tumor systems:

- BLENREP attaches to BCMA and enters myeloma cells to kill them directly
- One part in BLENREP can activate your immune system and direct it to attack myeloma cells
- When myeloma cells are destroyed in response to BLENREP, this helps your body's immune system recognize and kill other myeloma cells

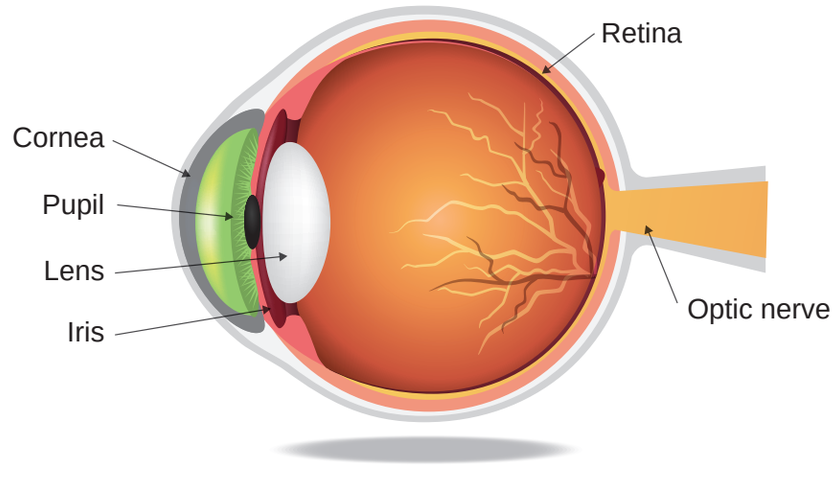
Why monitor changes in vision and eyes?

Clinical trials in myeloma patients found that the anti-cancer substance that is attached to the BLENREP antibody causes changes in vision and eyes. This is why you will be carefully monitored by an eye doctor to identify these types of changes.

Anatomy of the eye and how it relates to possible side effects in the cornea

To understand the vision and eye changes that have been reported with BLENREP treatment, it is 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 layer of the cornea are like your skin cells and regrow, which allows repair after injury.

Anatomy of the eye. The cornea covers the iris and pupil and helps focus most of the light that enters the eye. There are five layers of the cornea.

The cornea, specifically the corneal surface, is the part of the eye in which changes may occur when you are receiving BLENREP treatment.

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

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What to expect during treatment with BLENREP

The most common side effects found in the clinical trial

Below are the most common and potentially serious vision and eye changes following administration of BLENREP:

- Disorder of the cornea (71%)
  - Moderate to severe findings in the cornea were first observed about 36 days (range: 19 to 143 days) after starting BLENREP treatment.
  - Findings in the cornea which resulted in delay of the next dose and in dosage reduction were very common.
  - Findings in the cornea usually resolved after about 91 days (range: 21 to 201 days).
- Blurred vision (25%)
  - Of the patients who experienced blurred vision, most experienced mild to moderate symptoms.
- Dry eyes (15%)
  - Patients with a history of dry eyes had a stronger tendency to develop changes on the surface of the cornea.
  - It is important to tell your hematologist if you have a history of vision or eye problems.

Other common eye problems in patients receiving BLENREP and defined as affecting one person or more in 100 people but less than one in ten people, included:

- sensitivity to light (4%)
- eye irritation (3%)

Uncommon eye problems in patients receiving BLENREP and defined as affecting one person or more in 1,000 people but less than one in 100 people, included:

- ulcerative keratitis (ulcer in your cornea) (1%)
- infective keratitis (1%)

What to expect during treatment with BLENREP *(continued)*

If you get abnormal reactions in your cornea, please contact your hematologist.

My eyes are dry and itchy.

My vision is blurred.

My eyes are watery and irritated.

I cannot see very well.

My eyes are painful.

I feel more sensitive to light and am always squinting or shielding my eyes.

Other side effect that occurred in more the **20%** of people treated with BLENREP are low platelet count **(38%)**, low red blood cell count **(27%)**, nausea **(25%)**, fever **(23%)**, disturbed liver function (increased aspartate aminotransferase) **(21%)**, infusion related hypersensitivity reactions **(21%)**.

Infusion related reactions or allergy-like reactions may occur when you receive a BLENREP infusion.
These reactions usually develop within a few minutes and up to 24 hours after your treatment.

Platelets help your blood to clot. Reduced platelets can cause unusual bruising or bleeding.

These are not the only possible side effects of BLENREP. For full information about this medicine, read the patient leaflet enclosed with the medicine.

If you get any side effects while taking BLENREP, please contact your hematologist.

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Eye-related side effects:
Monitor, minimize, and modify treatment

You and the healthcare professionals who are treating you must take the following steps to monitor symptoms in your cornea, minimize them, and modify your BLENREP treatment so that unusual eye-related events can be treated if necessary.

The recommended dose of **BLENREP** is 2.5 mg/kg and it is given 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 your treatment is complete, because these drops can reduce your cornea symptoms.

For patients with dry eye symptoms: Your eye doctor may recommend additional therapies.

Do not wear contact lenses until end of treatment.

Use caution when driving or operating machines

Continue monitoring unusual reactions in the cornea after treatment and contact your hematologist if any symptoms occur.

An eye specialist must perform a visual acuity exam and a slit lamp exam.

First dose of **BLENREP** — **3 weeks** — Second dose of **BLENREP** — **3 weeks** — Third dose of **BLENREP** — **3 weeks** — Fourth dose of **BLENREP**

Treatment every **3 weeks** until disease progression or unacceptable toxicity.

Eye examinations and monitoring for possible symptoms in the eyes

Eye examination before first treatment

Before receiving treatment on the subsequent 3 treatment cycles, and as clinically indicated over the course of treatment

Eye examination before second dose

Eye examination before third dose

Eye examination before fourth dose

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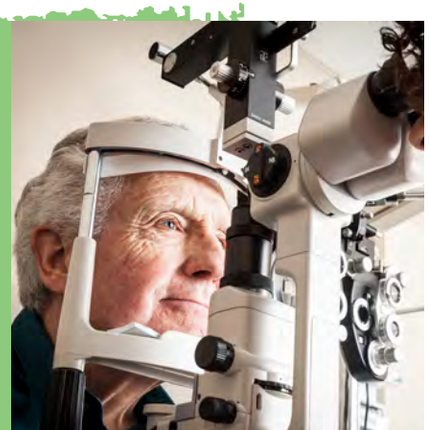
Eye-related side effects:
Monitor, minimize, and modify treatment *(continued)*

Monitor



Slit lamp exam

The surface of the eye is examined to identify damaged cells or any change to the surface of the eye.

Vision acuity exam

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

Minimize

Preservative-free artificial tears

There are many different lubricating eye drops (preservative-free artificial tears) available for purchase without a prescription. They are given to reduce the effect of BLENREP on your eyes. Your healthcare professional will be able to guide you about using them correctly.

Modify treatment

Your dose of medication may need to be modified or changed

If you develop moderate or severe changes in vision or eyes, your doctor may decide to modify your treatment (lower your dose or temporarily stop treatment until symptoms improve or resolve).

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Signs and symptoms of changes in vision and eyes

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

If your vision is normal, the image (or external visual stimulus) will look crisp without eye strain or irritation.

Tell your hematologist about any change or decline in your vision, including any of the following symptoms:

double vision

blurred vision

Additional symptoms that you must tell your hematologist about include:

- dry eyes
- eye pain or irritation
- itchy eyes
- sensitivity to light

Frequently asked questions

Question: **Which eye examinations will I need before starting treatment with BLENREP, and when should I have them?**
Answer: An eye doctor should perform eye examinations including a vision acuity exam and a slit lamp exam before you start treatment, before each of the subsequent three treatment cycles, and as clinically indicated while you are receiving treatment, as directed by your doctor.

Question: **In what ways could my eyes be affected during and after treatment with BLENREP?**
Answer: BLENREP can cause dry eyes, blurred vision, or other eye problems. Even if your vision seems fine, it is important that you get eye examinations during treatment with BLENREP because some changes can happen without symptoms and may only be seen in an eye examination.

Question: **When are the vision and eye changes related to BLENREP treatment expected to start? How long will they last?**
Answer: In the clinical trial, moderate to severe findings in the cornea were observed about 36 days (range: 19 to 143 days) after starting BLENREP treatment. These findings in the cornea resolved after about 91 days (range: 21 to 201 days).

Question: **Whom can I consult if the symptoms occur?**
Answer: Please consult your hematologist. Your BLENREP treatment may need to be modified.

Question: **Are there any restrictions on certain daily activities related to vision after starting BLENREP treatment?**
Answer: Do not wear contact lenses throughout treatment (which includes the transfusion and between infusions), unless your eye specialist tells you otherwise. **Also, do not drive or use machines** unless you are sure that your vision is not affected. Talk to your doctor if you are not sure.

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Frequently asked questions *(continued)*

Question: **Why does BLENREP affect the eyes?**
Answer: Although the exact reason is not known, BLENREP is taken up by cells throughout your body, including the cells on the surface of the cornea. In these cells, BLENREP could cause vision or eye changes.

Question: **How can the changes in my vision and eyes be treated?**
Answer: Use lubricant eye drops (preservative-free artificial tears) at least 4 times a day, starting on the day of your first infusion and continuing until your treatment is complete, because these drops can minimize the changes in your vision or eyes. If you have dry eye symptoms, your eye specialist may recommend additional therapies. Your hematologist may reduce your dose of BLENREP.

Question: **Will I have to stop my treatment if I get unusual reactions that affect my eyes and/or vision?**
Answer: Tell your hematologist if you have any changes in your vision and eyes. A lower dose of BLENREP may be recommended, or your treatment will be temporarily stopped until your symptoms improve. In cases of severe eye problems, stopping treatment completely will be considered.

Question: **Are there people who must not take BLENREP?**
Answer: BLENREP is not intended for use in children or adolescents under 18 years old, and in breastfeeding women or women who will begin breastfeeding within 3 months of their last dose of BLENREP. Do not use BLENREP if there is a known sensitivity to any of its ingredients.

Notes

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Understanding the vision and eyes changes that can occur when receiving BLENREP treatment

Overview of possible vision and eye changes that may occur with BLENREP, including:

- What side effects may occur
- What you should do if you get eye-related side effects
- A brief anatomy of the eye
- Signs and symptoms of changes in your vision and eyes
- Frequently asked questions

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Refer any medical question to your doctor or read the patient leaflet enclosed with the medicinal product and available on the website:
https://www.gov.il/he/service/israeli-drug-index
Any suspected side effects should be reported on the Ministry of Health website using the online form available at https://sideeffects.health.gov.il
Please also report to GSK Israel by email at il.safety@gsk.com

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