BLENREP

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist. Important safety information about eye-related issues is provided in the full CMI. Read before using this medicine.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being treated with BLENREP?

BLENREP contains the active ingredient belantamab mafodotin. BLENREP is used to treat multiple myeloma.

For more information, see Section 1. Why am I being treated with BLENREP? in the full CMI.

2. What should I know before I am treated with BLENREP?

Do not use if you have ever had an allergic reaction to BLENREP or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am treated with BLENREP? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BLENREP and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How will BLENREP be given to me?

BLENREP will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment. More instructions can be found in Section 4. How will BLENREP be given to me? in the full CMI.

5. What should I know while being treated with BLENREP?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are being treated with BLENREP. • Apply lubricating and moistening eye drops (preservative-free artificial tears) during treatment. • Contact your doctor if you develop any side effects or symptoms that worry you. • Attend all scheduled appointments and tell your doctor or nurse before you receive another infusion if you have developed any infusion-related reactions. • Tell your doctor if you are taking, have recently taken or might take any other medicines. • Tell your doctor if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.
Things you should not do	• Do not stop treatment with this medicine suddenly. • Do not use contact lenses while receiving treatment with BLENREP unless instructed by your eye care professional. • Do not breastfeed during treatment and for 3 months after your last dose of BLENREP.
Driving or using machines	• BLENREP can cause problems with vision that can affect your ability to drive or use machines. Do not drive or use machines unless you are sure your vision is not affected.
Looking after your medicine	• BLENREP will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage.

For more information, see Section 5. What should I know while being treated with BLENREP? in the full CMI.

6. Are there any side effects?

This medicine can cause side effects, although not everybody gets them. Common side effects include fever, fatigue, anaemia, nausea, diarrhoea, vomiting, cold or cold-like symptoms, foamy or frothy urine, abnormal blood tests and abnormal levels of creatine phosphokinase. Serious side effects include eye-related issues, abnormal bruising or bleeding (thrombocytopenia), pneumonia, disorder of the blood vessels in the liver and infusion-related reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BLENREP can cause changes to the surface of your eye which can result in changes in vision, blurred vision, and dry eyes. You should have an eye examination by an eye care professional before each dose of BLENREP. Your doctor may request additional eye tests while on treatment with BLENREP. If you have not had vision changes or other eye changes, during the first six doses of BLENREP, your doctor may reduce eye exams to approximately every three months with additional eye exams when needed. 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.

Tell your doctor if you notice changes with your vision. Your doctor may reduce the dose or change the time between doses. Your doctor might also ask you to see an eye care professional.

BLENREP

Active ingredient(s): *Belantamab mafodotin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BLENREP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BLENREP.**

Where to find information in this leaflet:

1. Why am I being treated with BLENREP?

BLENREP contains the active ingredient belantamab mafodotin. Belantamab mafodotin is a monoclonal antibody connected to an anticancer medicine that can kill multiple myeloma cells. The monoclonal antibody is a protein designed to find the multiple myeloma cells in your body and bind to them. Once attached to the cancer cells, the anticancer medicine is released and kills the cancer cells.

BLENREP is used to treat adults who have cancer of the bone marrow called multiple myeloma.

BLENREP will be given to you together with other anticancer medicines used to treat multiple myeloma:

- bortezomib and dexamethasone, or
- pomalidomide and dexamethasone.

2. What should I know before I am treated with BLENREP?

Warnings

Do not use BLENREP if:

- you are allergic to belantamab mafodotin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other conditions

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not breastfeed during treatment and for 3 months after your last dose of BLENREP. It is not known if the medicine passes into breastmilk.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start treatment with BLENREP. You must use effective contraception during treatment and for 4 months after your last dose of BLENREP.

If you are a man who could father a child, you must use effective contraception during treatment and for 6 months after your last dose of BLENREP.

Children and adolescents

This medicine is not intended for use in children or adolescents below 18 years of age.

Eye-related issues

- BLENREP can cause changes to the surface of your eye which can result in changes in vision, blurred vision, and dry eyes.
- You should have an eye examination by an eye care professional before each of the first six doses of BLENREP.

Abnormal bruising and bleeding

- BLENREP can decrease the number of blood cells called *platelets* which help to clot your blood.

- Symptoms of low platelet counts (*thrombocytopenia*) include:
    - abnormal bruising under the skin,
    - bleeding longer than usual after a blood test or cut to the skin,
    - bleeding from your nose or your gums or more serious bleeding.
- Your doctor will ask you to have a blood test before you start treatment, and regularly during treatment with BLENREP, to check that your platelet levels are normal.

Infusion-related reactions

If you have previously had a reaction to an infusion of BLENREP or any other medicine, tell your doctor or nurse before you receive another infusion.

Hepatitis B reactivation

Check with your doctor if you have a history of hepatitis B infection. Reactivation of the hepatitis B virus can occur in patients treated with BLENREP.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with BLENREP and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BLENREP.

4. How will BLENREP be given to me?

How much will be given

- Your doctor will decide on the correct dose of BLENREP. The dose is calculated based on your body weight.
- BLENREP will be given together with other medicines used to treat multiple myeloma in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.

When BLENREP will be given

- Your doctor will administer BLENREP as an intravenous infusion over approximately 30 minutes.
- Your doctor will decide how many treatments you need.

If a dose of BLENREP is missed

BLENREP should be used regularly at the same time as scheduled by your doctor. **It is very important that you do not miss a dose of this medicine, to make sure your treatment works.**

If you miss an appointment, make another one as soon as possible. Contact your doctor or hospital as soon as possible to re-schedule your appointment.

If you are given more BLENREP than you should

As BLENREP is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. If you think you have been given too much BLENREP you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being treated with BLENREP?

Things you should do

- If you miss an appointment, contact your doctor or hospital immediately to reschedule.
- Tell your doctor or nurse if you are taking, have or might take any other medicines.
- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- It is important to read the patient leaflets for the other anticancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.
- If you have previously had a reaction to an infusion of BLENREP, or any other medicine, tell your doctor or nurse before you receive another infusion.
- Apply lubricating and moistening eye drops (preservative-free artificial tears) before your infusion. Use as instructed.
- Continue to use the eye drops at least 4 times a day whilst you are receiving treatment with BLENREP.

Call your doctor straight away if you:

- think you may be having an allergic reaction.
- experience blurred vision or other eye problems.
- develop abnormal bleeding or bruising, or any symptoms that worry you.
- develop any lung problems or any breathing-related symptoms that worry you.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using BLENREP.

Things you should not do

- Do not use contact lenses while you are receiving treatment unless instructed to do so by your eye care professional.
- Do not miss a dose of this medicine.
- Do not breastfeed during treatment.

Eye-related issues

- Your doctor may request further eye tests whilst on treatment with BLENREP.

- 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.
- Inform your doctor if you notice changes with your vision. Your doctor may reduce the dose or change the time between doses. Your doctor might also ask you to see an eye care professional.
- Some eye problems may feel uncomfortable or painful but tend to get better over time, after your doctor changes your dose.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BLENREP affects you.

BLENREP can cause problems with your vision that can affect your ability to drive or use machines.

Do not drive or use machines unless you are sure your vision is not affected. Talk to your doctor if you are not sure.

Looking after your medicine

BLENREP will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage.

Unopened vials:

Store in the original container.

Store in a refrigerator (2°C to 8°C).

Reconstituted solution:

The reconstituted solution can be stored for up to 4 hours at room temperature (20°C to 25°C) or stored in a refrigerator (2°C to 8°C) for up to 4 hours.

Do not freeze.

Diluted solution:

If not used immediately, the diluted solution can be stored in a refrigerator (2°C to 8°C) prior to administration for up to 24 hours.

Do not freeze.

The diluted infusion solution may be kept at room temperature (20°C to 25°C) for a maximum of 6 hours (including infusion time).

When to discard your medicine (as relevant)

Your healthcare professional will be responsible for discarding BLENREP.

Getting rid of any unwanted medicine

Your healthcare professional will be responsible for discarding BLENREP.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General disorders: • fever, • general weakness • feeling tired (fatigue) • cold or cold-like symptoms such as cough, runny nose or sore throat (upper respiratory tract infection) **Gastrointestinal disorders:** • diarrhoea • nausea • constipation • vomiting **Renal and urinary disorders:** • foamy, frothy, or bubbly-looking urine indicating a high level of protein in your urine (albuminuria) • Urinary tract infection **Change in blood test results:** These may be found when your doctor tests for them. • abnormal levels of creatine phosphokinase • abnormal blood test indicating liver problems (aspartate aminotransferase, gamma glutamyltransferase, alanine aminotransferase) • low number of red blood cells which carry oxygen in the blood (anaemia), causing weakness and fatigue • low number of white blood cells in the blood which help to fight infections (lymphopenia, leukopenia, neutropenia)	**Speak to your doctor if you have any of these less serious side effects or if they worry you.**

Serious side effects

Serious side effects	What to do
Eye disorders: • Eye-related issues, including: • changes to the surface of your eye • blurred vision • dry eyes • feeling of something in your eye (foreign body sensation in eyes) • eye irritation • decreased vision • sensitivity to light (photophobia)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• eye pain • increased tear production (lacrimation) • double vision (diplopia) • discomfort in eye • eye sores, possibly with infection (infective keratitis and ulcerative keratitis) • itchy eyes (eye pruritus) **Gastrointestinal disorders:** • diarrhoea (significant episodes) **Hepatobiliary disorders:** • disorder of the blood vessels in the liver (porto-sinusoidal vascular disorder). This can lead to abnormal liver blood tests and long-term problems such as increased pressure of the blood vessels in the abdomen (portal hypertension), swelling of blood vessels (varices), or a build-up of fluid in the abdomen which can cause abdominal pain, weight gain or swelling of the abdomen (ascites). **Abnormal bruising or bleeding:** Low number of a type of blood cells called platelets which help to clot blood (thrombocytopenia), which may be tested for by your doctor. **Lung problems (pneumonitis):** Severe and life-threatening inflammation of the lungs has occurred in some people who received BLENREP. Possible symptoms of lung inflammation include: • shortness of breath • chest pain • new onset or worsening cough Your doctor may decide to hold or stop treatment with BLENREP if you have these symptoms. **Infusion-related reactions:** BLENREP is given by a drip (infusion) into a vein. Some people who receive infusions may develop allergic-like reactions when they receive an infusion. These usually develop within minutes or hours but may	

Serious side effects	What to do
develop up to 24 hours after treatment. Symptoms include: • flushing • chills • fever • difficulty breathing • rapid heartbeat • drop in blood pressure	

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BLENREP contains

Active ingredient (main ingredient)	Belantamab mafodotin
Other ingredients (inactive ingredients)	Sodium citrate dihydrate Citric acid monohydrate Trehalose dihydrate Disodium edetate Polysorbate 80

Do not receive this medicine if you are allergic to any of these ingredients.

What BLENREP looks like

BLENREP is presented as a white to yellow powder in a glass vial with a rubber stopper and a plastic removable cap. Each carton contains one vial.

One vial of powder contains 70 or 100 mg of belantamab mafodotin. After reconstitution the solution contains 50 mg per mL belantamab mafodotin.

BLENREP 70 mg vials: AUST R 464326

BLENREP 100 mg vials: AUST R 464325

Who distributes BLENREP

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,
Abbotsford, Victoria, 3067
Phone: 1800 033 109
www.gsk.com.au

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