PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

BLENREP 100 mg

Powder for concentrate for solution for infusion

Each dose (vial) contains:
belantamab mafodotin 100 mg

In addition to this leaflet, BLENREP also has a patient guide that will be given to you by your physician. This guide contains important safety information that you need to know and that you should follow before starting and during treatment with BLENREP. Carefully read this guide and the patient information leaflet before using this medicine. Keep the guide in case you need to read it again.

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

BLENREP is indicated in adults for the treatment of relapsed or refractory multiple myeloma:

- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy, and
- in combination with pomalidomide and dexamethasone in patients who have received at least one prior therapy that included lenalidomide.

Therapeutic group: antineoplastic agents, monoclonal antibodies, antibody conjugated with the medicine.

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

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient (belantamab mafodotin) or to any of the additional ingredients contained in this medicine (listed in section 6).

→ **Tell your physician** if you think this situation applies to you.

Special warnings regarding use of the medicine

Talk to your physician or nurse before you are given BLENREP if you have:

Eye-related problems

BLENREP can cause changes to the surface of your eye which can result in changes in vision, blurred vision, and dry eyes (see additional information in the “Tests and follow-up” section).

→ **Do not use contact lenses** while you are receiving treatment unless instructed to do so by your eye care professional.

Your physician will ask you to use eye drops called *preservative-free artificial tears* at least 4 times a day during treatment to moisten and lubricate your eyes. You should apply them as instructed.

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

→ **Contact your physician** if you have blurred vision or other eye problems.

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

→ **Tell your physician** if you develop abnormal bleeding or bruising, or any symptoms that worry you.

Infusion-related reactions

BLENREP is given by a drip (*infusion*) into a vein. Some people who receive infusions develop *infusion-related reactions*.

→ **See** “Infusion-related reactions” in section 4.

If you have previously had a reaction to an infusion of BLENREP, or any other medicine:

→ **Tell your physician or nurse** before you receive another infusion.

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 physician may decide to hold or stop treatment with BLENREP if you have these symptoms.

→ **Tell your physician** if you develop any lung problems or any breathing-related symptoms that worry you.

If you have or have previously had a Hepatitis B infection

Talk to your physician if you might have or previously had a Hepatitis B infection. This medicine may cause a reactivation of the infection. Your physician may check you for signs of infection during treatment.

→ **Tell your physician** if you notice any of the following symptoms: worsening tiredness, yellowing of the skin or the white part of the eyes, and/or dark urine.

It is important that you read the patient leaflets for the other medicines you may be receiving. If you have any questions about these medicines, ask your physician.

Children and adolescents

There is no information about the safety and efficacy of BLENREP in children and adolescents under the age of 18. This medicine is not intended for use in children or adolescents below 18 years of age.

Tests and follow-up

You should have an eye examination by an eye care professional before each of the first four doses of BLENREP. Your physician 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.

Your physician 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.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

Pregnancy, breast-feeding and fertility

Pregnancy and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby:

→ **Consult with your physician** before you are given this medicine.

If you are a woman who could become pregnant:

- Your physician 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.

Women being treated with this medicine who wish to have children are advised to seek fertility counselling.

There are no data from the use of this medicine in pregnant women.
BLENREP is not recommended for use during pregnancy unless the benefit to the mother outweighs the potential risks to the foetus.

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.

Men being treated with this medicine who wish to have children are advised to seek fertility counselling.

Breast-feeding
You must not breast-feed during treatment and for 3 months after your last dose of BLENREP.
It is not known if the medicine passes into breast milk. Talk to your physician about this.

Driving and using machines
BLENREP can cause problems with vision that could affect your ability to drive or use machines. The physician will advise you to use caution when driving or operating machines.
→ **Do not drive or use machines** unless you are sure your vision is not affected. Talk to your physician if you are not sure.

Important information about some of the ingredients in the medicine
BLENREP contains sodium
The preparation contains less than 1 mmol sodium (23 mg) per dose, that is to say, it is essentially “sodium-free”.
BLENREP contains polysorbate 80
Each vial of reconstituted solution contains 0.2 mg of polysorbate 80 per mL.
Polysorbates may cause allergic reactions. Tell your physician if you have any known allergies.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.
The dosage and treatment regimen will be determined by the physician only.
Your physician will decide on the correct dose of BLENREP. The dose is calculated based on your body weight.
BLENREP is given by your physician or nurse as a drip into a vein (intravenous infusion).
BLENREP is administered as a 30-minute infusion.

When BLENREP is given together with bortezomib and dexamethasone,
BLENREP will be given once every 3 weeks with a starting dose of 2.5 mg/kg.
BLENREP is administered from Cycle 1 until completion of treatment, while bortezomib and dexamethasone are administered for the first 8 Cycles. Each 21-day period is considered one treatment cycle

When BLENREP is given together with pomalidomide and dexamethasone, BLENREP will be given once every 4 weeks with a starting dose of 2.5 mg/kg given once in Cycle 1. From Cycle 2 onwards, BLENREP will be given at a dose of 1.9 mg/kg. Each 28-day period is considered one treatment cycle.

You should continue the cycles of treatment until your physician tells you to stop. Your physician may change the dose and the total number of treatment cycles, depending on your response to the treatment and on the occurrence of certain side effects.

Do not exceed the recommended dose.

Before your infusion, you must apply lubricating and moistening eye drops (*preservative-free artificial tears*). You must continue to use the eye drops at least 4 times a day whilst you are receiving treatment with BLENREP.

If you have accidentally been given a higher dosage

This medicine will be given by your physician or nurse. In the unlikely event that you are given too much (an overdose), your physician will check you for side effects.

If you missed a dose of the medicine

It is very important to go to all your appointments, to make sure your treatment works. If you miss an appointment, make another one as soon as possible.

→ Contact your physician or hospital as soon as possible to re-schedule your appointment.

Adhere to the treatment regimen recommended by your physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of BLENREP may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Infusion-related reactions

Some people may have allergic-like reactions when they receive an infusion. These usually develop within minutes or hours but may develop up to 24 hours after treatment.

Symptoms include:

• flushing
• chills
• fever
• difficulty breathing
• rapid heartbeat
• drop in blood pressure

→ **Get medical help immediately** if you think you may be having a reaction.

Other side effects

BLENREP when given with bortezomib and dexamethasone

Tell your physician or nurse if you notice any of the following side effects:

Very common side effects

These may affect **more than 1 in 10** people:

- low number of a type of blood cell called platelets which help to clot blood (*thrombocytopenia*), which may cause abnormal bruising and bleeding.

→ **Read the information** under "Abnormal bruising and bleeding" in section 2 of this leaflet.

- eye-related problems, including decreased vision, blurred vision, changes to the surface of your eye, dry eyes, sensitivity to light (*photophobia*), feeling of something in your eye (*foreign body sensation in the eyes*), eye irritation, eye pain, and problems with vision.

→ **Read the information** under "Eye-related problems" in section 2 of this leaflet.

- cold or cold-like symptoms such as cough, runny nose or sore throat (*upper respiratory tract infection*).
- infection of the lungs (*pneumonia*).
- fever
- 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 (*neutropenia, lymphopenia, and leukopenia*).
- abnormal blood test results indicating liver problems (alanine aminotransferase, aspartate aminotransferase, and gamma glutamyltransferase).
- diarrhoea
- feeling tired (*fatigue*)
- nausea.

Common side effects

These may affect **up to 1 in 10** people:

- other eye-related problems including increased tear production (*lacrimation*), double vision (*diplopia*), itchy eyes (*eye pruritus*), and eye discomfort.
- foamy, frothy, or bubbly-looking urine indicating a high level of protein in your urine (*albuminuria*).
- vomiting
- abnormal blood levels of creatine phosphokinase
- infusion-related reactions.

Uncommon side effects

These may affect **up to 1 in 100** people:

- disorder of the blood vessels in the liver (*porto-sinusoidal vascular disorder*). This can lead to abnormal liver blood test results 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*).
- eye sores, possibly with infection (*corneal ulcers, including infective keratitis and ulcerative keratitis*).
- recurrence of Hepatitis B infection when you have had Hepatitis B in the past (Hepatitis B reactivation, see section 2 for more information).

<u>BLENREP when given with pomalidomide and dexamethasone</u>

Tell your physician or nurse if you notice any of the following side effects:

Very common side effects

These may affect **more than 1 in 10** people:

- eye-related problems, including decreased vision, changes to the surface of your eye, blurred vision, dry eyes, feeling of something in your eye (*foreign body sensation in the eyes*), eye irritation, sensitivity to light (*photophobia*), eye pain, and problems with vision.

→ **Read the information** under “Eye-related problems” in section 2 of this leaflet.

• low number of a type of blood cell called platelets which help to clot blood (*thrombocytopenia*), which may cause abnormal bruising and bleeding.

→ **Read the information** under “Abnormal bruising and bleeding” in section 2 of this leaflet.

• low number of white blood cells in the blood which help to fight infections (*neutropenia*)

• cold or cold-like symptoms such as cough, runny nose or sore throat (*upper respiratory tract infection*).

• infection of the lungs (*pneumonia*).

• feeling tired (*fatigue*)

• fever

• low number of red blood cells which carry oxygen in the blood (*anaemia*), causing weakness and fatigue.

• abnormal blood test results indicating liver problems (alanine aminotransferase and aspartate aminotransferase).

• diarrhoea

• nausea.

Common side effects

These may affect **up to 1 in 10** people:

• low number of white blood cells in the blood which help to fight infections (*leukopenia and lymphopenia*).

• abnormal blood test results indicating liver problems (gamma *glutamyltransferase*).

• other eye-related problems including increased tear production (lacrimation), double vision (*diplopia*), itchy eyes (*eye pruritus*), eye sores, possibly with infection (*corneal ulcers including infective keratitis and ulcerative keratitis*), and eye discomfort.

• vomiting

• infusion-related reactions

• foamy, frothy, or bubbly-looking urine indicating a high level of protein in your urine (*albuminuria*).

Uncommon side effects

These may affect **up to 1 in 100** people:

• disorder of the blood vessels in the liver (*porto-sinusoidal vascular disorder*). This can lead to abnormal liver blood test results 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*).

• recurrence of Hepatitis B infection when you have had Hepatitis B in the past (Hepatitis B reactivation, see section 2 for more information).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

• Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

• Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• Store in a refrigerator (2°C–8°C).

For storage instructions after preparation, see the preparation instructions for healthcare professionals at the end of the leaflet.

- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Trehalose dihydrate, trisodium citrate dihydrate, citric acid monohydrate, polysorbate 80 and disodium edetate dihydrate.
  Also see section 2 in this leaflet – "Important information about some of the ingredients in the medicine".
- What the medicine looks like and the contents of the package:
  BLENREP is presented as a white to yellow powder in a glass vial with a rubber stopper and a removable plastic cap. Each carton contains one vial.
- License holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 180-79-38455

Revised in January 2026

Blenrep 100mg PT V2C

The following information is intended for healthcare professionals only: Step-by-step instructions for use and handling, reconstitution, and administration

The trade name and batch number of the administered product should be clearly recorded in the patient file.

Preparation of solution for infusion

Blenrep is a cytotoxic anticancer medicinal product. Proper handling procedures must be followed. Use aseptic technique for the reconstitution and dilution of the dosing solution.

Calculate the dose (mg), total volume (mL) of solution required and the number of vials needed based on the patient's actual body weight (kg).

Reconstitution

1. Remove the vial(s) of Blenrep from the refrigerator and allow to stand for approximately 10 minutes to reach room temperature.
2. Reconstitute each 100 mg vial with 2 mL of sterile water for injection to obtain a concentration of 50 mg/mL. Gently swirl the vial to aid dissolution. DO NOT SHAKE.
3. Visually inspect the reconstituted solution for particulate matter and discoloration. The reconstituted solution should be a clear to opalescent, colourless to yellow to brown liquid. Discard the reconstituted vial if extraneous particulate matter other than translucent to white proteinaceous particles is observed.

Dilution Instructions for Intravenous Use

1. Withdraw the necessary volume for the calculated dose from each vial.
2. Add the necessary amount of Blenrep to the infusion bag containing 250 mL of sodium chloride 9 mg/mL (0.9%) solution for injection. Mix the diluted solution by gentle inversion. The final concentration of the diluted solution should be between 0.2 mg/mL to 2 mg/mL. DO NOT SHAKE.

3. Discard any unused reconstituted solution of Blenrep left in the vial.

If the diluted solution is not used immediately, it may be stored in a refrigerator
(2°C to 8°C) for up to 24 hours prior to administration. If refrigerated, allow the diluted solution to equilibrate to room temperature prior to administration. The diluted solution may be kept at room temperature (20°C to 25°C) for a maximum of 6 hours (including infusion time).

Administration Instructions

1. Administer the diluted solution by intravenous infusion over a minimum of 30 minutes using an infusion set made of polyvinyl chloride or polyolefin.
2. Filtration of the diluted solution is not required. However, if the diluted solution is filtered, polyethersulfone (PES) based filter is recommended.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.