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

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

BLENREP

Powder for concentrate for solution for infusion

Each dose (vial) contains:
belantamab mafodotin 100 mg

In addition to the leaflet, BLENREP has patient guides which will be given to you by your physician. These guides contain important safety information which you need to know before and during treatment with BLENREP and to follow. Read the guides and patient leaflet before starting to use this medicine. The guides should be kept for further reference if necessary.

For the list of the inactive and allergenic ingredients in the preparation, 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 for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
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 BLENREP if:
- you are sensitive (allergic) to belantamab mafodotin or to any of the additional ingredients contained in this medicine (listed in section 6).

→**Tell your physician** if you think any of these apply to you.

Special warnings regarding use of the medicine

Eye problems
BLENREP can cause dry eyes, blurred vision or other eye problems. You should have an eye examination by an eye specialist before starting treatment and for the next three 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.
→**Do not use contact lenses** while you are receiving treatment.
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.
If you notice changes with your vision, your physician may hold treatment with BLENREP or adjust the dose or ask you to see an eye specialist. Your physician may decide to stop treatment with BLENREP.
→**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 test
- bleeding from your nose or your gums or more serious bleeding

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.
→**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.

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

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, fertility and breast-feeding
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 and consider options to freeze eggs/embryos before treatment.
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 are advised to have sperm samples frozen and stored before treatment.
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 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 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 100 mg dose, that is to say, it is essentially "sodium-free".

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.
The recommended dosage is usually 2.5 mg of BLENREP per kilogram of your body weight. It is given by your physician or nurse as a drip into a vein (intravenous infusion) every three weeks.

Do not exceed the recommended dose.

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

If you were given too much BLENREP
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 a dose of BLENREP is missed
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 any 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
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 problems, including disorder of the cornea of the eye (keratopathy), blurred vision, and dry eyes

→**Read the information** under "Eye problems" in Section 2 of this leaflet.
- low number of a type of blood cell called platelets which help to clot blood (thrombocytopenia), causing abnormal bruising and bleeding

→**Read the information** under "Abnormal bruising and bleeding" in Section 2 of this leaflet.
- 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 (lymphopenia, leukopenia, neutropenia)
- abnormal blood levels of enzymes indicating liver problems (aspartate aminotransferase, gamma glutamyltransferase)
- nausea
- feeling tired (fatigue)
- diarrhoea.

Common side effects: these may affect **up to 1 in 10** people
- cold or cold-like symptoms such as cough, runny nose or sore throat
- vomiting
- abnormal levels of creatine phosphokinase
- sensitivity to light (photophobia)
- eye irritation
- foamy, frothy, or bubbly-looking urine indicating a high level of protein in the urine (albuminuria).

Uncommon side effects: these may affect **up to 1 in 100** people
- eye sores, possibly with infection (ulcerative and infective keratitis).

Side effects of unknown frequency (frequency has not been determined yet): frequency cannot be estimated from the available data
- inflammation of the lungs (pneumonitis).

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).
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, this medicine also contains:
  Trehalose dihydrate, trisodium citrate dihydrate, citric acid, polysorbate 80, 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 Manufacturing S.p.A, Parma, Italy.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  168-62-36882

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