Package leaflet: Information for the patient

BLENREP® 100 mg powder for concentrate for solution for infusion

(belantamab mafodotin)

The name of your medicine is Blenrep 100 mg powder for concentrate for solution for infusion but will be referred to as BLENREP throughout this leaflet.

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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What BLENREP is and what it is used for
2. What you need to know before you are given BLENREP
3. How BLENREP is given
4. Possible side effects
5. How to store BLENREP
6. Contents of the pack and other information

1. What BLENREP is and what it is used for

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.

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

2. What you need to know before you are given BLENREP

Do not receive BLENREP:
- if you are allergic to belantamab mafodotin or any of the other ingredients of this medicine (listed in section 6).

►**Check with your doctor** if you think this applies to you.

Warnings and precautions

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 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.

►**Do not use contact lenses** while you are receiving treatment.

Your doctor 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 doctor may hold treatment with BLENREP or adjust the dose or ask you to see an eye specialist. Your doctor may decide to stop treatment with BLENREP.

►**Contact your doctor** 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 platelets 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 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.

►**Tell your doctor** 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 doctor 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 doctor may decide to hold or stop treatment with BLENREP if you have these symptoms.

►**Tell your doctor** 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.

Other medicines and BLENREP

►**Tell your doctor** if you are taking, have recently taken or might take any other medicines.

Pregnancy and fertility

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

►**Tell your doctor** before you are given this medicine.

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.

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 doctor 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 doctor if you are not sure.

BLENREP contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg dose, that is to say essentially "sodium-free".

3. How BLENREP is given

Your doctor will decide on the correct dose of BLENREP. The dose is calculated based on your body weight.

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

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 given more BLENREP than you should

This medicine will be given by your doctor or nurse. In the unlikely event that you are given too much (an overdose) your doctor 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 doctor or hospital as soon as possible to re-schedule your appointment.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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 doctor or nurse if you notice any of the following side effects:

Very common: 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: 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 your urine (*albuminuria*)

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

Unknown: frequency cannot be estimated from the available data
- inflammation of the lungs (pneumonitis)
- decreased sensitivity of the cornea of the eye (hypoesthesia of cornea)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.** By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BLENREP

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

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. Contents of the pack and other information

What BLENREP contains

The active substance is belantamab mafodotin. One vial of powder contains 100 mg of belantamab mafodotin. After reconstitution the solution contains 50 mg belantamab mafodotin per ml.

The other ingredients are sodium citrate, citric acid, trehalose dihydrate, disodium edetate and polysorbate 80 (see section 2 "BLENREP contains sodium").

What BLENREP looks like and contents of the pack

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.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder
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Blenrep 100 mg powder for concentrate for solution for infusion
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POM

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This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) will review new information on this medicine at least every year and this leaflet will be updates as necessary.

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format suitable for you.

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 should be followed. Use aseptic technique for the reconstitution and dilution of the dosing solution.

The recommended dose of BLENREP is 2.5 mg/kg administered as an intravenous infusion once every 3 weeks.

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 vial with 2 ml of water for injections 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.