Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]BLENREP

belantamab mafodotin for injection

This patient medication information is written for the person who will be taking **BLENREP**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **BLENREP**, talk to a healthcare professional.

This medicine has been prescribed for you personally. Your cancer is being treated with BLENREP together with other drugs. Read the leaflets of the other drugs as well as this one. This will help you understand the information related to your treatment.

Serious warnings and precautions box

- **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 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.

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

  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.

  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.

What BLENREP is used for:

BLENREP is a prescription medicine used to treat a type of cancer called multiple myeloma in adults 18 years or older. BLENREP is given after you have tried one or more other treatments that were unsuccessful or when the cancer has come back.

Multiple myeloma is a cancer of plasma cells (a type of white blood cell in the bone marrow that produces antibodies).

How BLENREP works:

BLENREP contains the active substance, belantamab mafodotin, which is made up of two types of medicine that are attached to each other. One part is a type of medicine called a monoclonal antibody. The monoclonal antibody is connected to the other part which is an anticancer medicine that can kill multiple myeloma cells. In BLENREP, the monoclonal antibody, belantamab, 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 medicine is released to kill the cancer cells.

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

- bortezomib and dexamethasone.
- pomalidomide and dexamethasone.

The ingredients in BLENREP are:

Medicinal ingredients: belantamab mafodotin.

Non-medicinal ingredients: citric acid monohydrate; disodium edetate dihydrate; polysorbate 80; trehalose dihydrate; trisodium citrate dihydrate.

BLENREP comes in the following dosage form:

BLENREP is provided as a powder in a single-use vial that is reconstituted and diluted for intravenous Infusion.

BLENREP is a white to yellow powder in a glass vial with a rubber stopper and a plastic removable cap.

Each carton contains one vial of 70 mg or 100 mg of belantamab mafodotin. After reconstitution, the solution for injection contains 50 mg belantamab mafodotin per mL.

Do not use BLENREP if:

- You are allergic to any of the ingredients in BLENREP.
- If you are not sure, talk to your doctor or nurse before you are given BLENREP.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BLENREP. Talk about any health conditions or problems you may have, including:

- if you are pregnant, think you may be pregnant or are planning to have a baby, **tell your healthcare professional** before you are given this medicine.
- if you are a woman who could become pregnant, you must use effective contraception during treatment and for 4 months after your last dose of BLENREP. Your healthcare professional will ask you to take a pregnancy test before you start treatment with 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.

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 healthcare professional before you are given this medicine.

Other warnings you should know about:

Eye-related changes

- 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 (for example ophthalmologist (eye doctor) or optometrist) before each dose of BLENREP or more frequently as clinically indicated. 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.
- Your healthcare professional may request additional eye tests during the course of your 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 in an eye examination.
- Do not use contact lenses while you are receiving BLENREP unless instructed to do so by your eye care professional.
- 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.
- Tell your healthcare professional if you notice changes with your vision. Your healthcare professional may reduce the dose or change the time between doses. Your doctor may ask you to see an eye care professional.
- Contact your healthcare professional if you have blurred vision or other eye changes.
- BLENREP can cause changes with vision that can affect your ability to drive or use machines. If you are experiencing changes in your vision, do not drive or use machines. Talk to your healthcare professional about this.
- Additional information on ocular adverse reactions and their management is available in educational materials for patients and prescribers. These educational materials are available upon request by contacting GSK Medical Information at 1-800-387-7374.

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) may include abnormal bruising under the skin, bleeding longer than usual after a blood test or cut to the skin, and bleeding from your nose or your gums or more serious bleeding.
- Your healthcare professional 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 healthcare professional if you notice abnormal bleeding or bruising, or any symptoms that worry you.

Infections

- BLENREP, in combination with bortezomib and dexamethasone or pomalidomide and dexamethasone, may increase the occurrence of infections. These infections could be severe or life-threatening. Tell your doctor right away if you develop fever, feel very tired, have a cough, or have flu-like symptoms.

Infusion-related reactions

- BLENREP is given by a drip (infusion) into a vein. Some people who receive infusions develop infusion-related reactions.
- If you have previously had a reaction to an infusion of BLENREP, or any other medicine: Tell your healthcare professional 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 healthcare professional 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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take BLENREP:

BLENREP will be given to you by a healthcare professional who is experienced in cancer treatment.

Your healthcare professional will give you BLENREP as a drip into a vein (*intravenous infusion*) for about 30 minutes.

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 during your treatment with BLENREP.

Usual dose:

Your healthcare professional will decide on the correct dose of BLENREP for you. The dose is calculated based on your body weight.

Overdose:

BLENREP will be given by your healthcare professional. In the unlikely event that you are given too much (an overdose), your doctor will check you for side effects.

If you think you, or a person you are caring for, have taken too much BLENREP contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

It is very important to go to all your appointments, to make sure your treatment works. If you miss an

appointment to receive BLENREP:

- Contact your healthcare professional or hospital or clinic immediately to reschedule your appointment.

Possible side effects from using BLENREP:

Like all medicines, this medicine can cause side effects, although not everybody gets them. These are not all the possible side effects you may have when taking BLENREP in combination with bortezomib and dexamethasone or pomalidomide and dexamethasone. If you experience any side effects not listed here, tell your healthcare professional.

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.

In combination with bortezomib and dexamethasone

Very common (more than 1 in 10) side effects include: upper respiratory tract infections with cold or cold-like symptoms (cough, runny nose or sore throat); fever; weakness and fatigue from low red blood cell count (anemia); infections from low white blood cell count (neutropenia, lymphopenia, and leukopenia) ; abnormal liver enzyme levels which may be a sign of liver problems (alanine aminotransferase, aspartate aminotransferase, gamma glutamyltransferase); diarrhea; feeling tired (fatigue); nausea.

Refer to the Serious Side Effects table below if you experience eye-related side effects.

Common (up to 1 in 10) side effects include: eye-related issues including tear production (lacrimation), double vision (diplopia), itchy eyes (eye pruritus), discomfort in the eye; foamy, frothy or bubbly-looking urine which may be a sign of high level of protein in your urine (albuminuria); vomiting; abnormal levels of creatine phosphokinase; infusion-related reactions.

Uncommon (up to 1 in 100) side effects include: eye sores, possibly with infection (infective keratitis).

In combination with pomalidomide and dexamethasone

Very common (more than 1 in 10) side effects include: upper respiratory tract infections with cold or cold-like symptoms (cough, runny nose or sore throat); feeling tired (fatigue); fever; weakness and fatigue from low red blood cell count (anemia); abnormal liver enzyme levels which may be a sign of liver problems (alanine aminotransferase and aspartate aminotransferase); diarrhea; nausea.

Refer to the Serious Side Effects table below if you experience eye-related side effects.

Common (up to 1 in 10) side effects include: infections from low white blood cell count (lymphopenia, and leukopenia); abnormal liver enzyme levels which may be a sign of liver problems (gamma glutamyltransferase); eye-related issues including tear production (lacrimation), double vision (diplopia), itchy eyes (eye pruritus), eye sores, possibly with infection (corneal ulcers including infective keratitis and ulcerative keratitis), discomfort in the eye; vomiting; infusion-related reactions; foamy, frothy or bubbly-looking urine which may be a sign of high level of protein in your urine (albuminuria).

For both combinations

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Very common			
Eye-related changes: changes to the surface of your eye, blurred vision, dry eyes, feeling of something in your eye (foreign body sensation in eyes), eye irritation, sensitivity to light (photophobia), eye pain, decreased vision, and changes with vision.		✓	
Infection of the lungs (pneumonia): fever, trouble breathing, chest pain, and new onset or worsening cough.		✓	✓
Low platelet counts (thrombocytopenia): abnormal bruising under the skin, bleeding longer than usual after a blood test or cut to the skin, and bleeding from your nose or your gums or more serious bleeding.		✓	✓
Unknown			
Lung problems (pneumonitis): trouble breathing, chest pains and dry cough, due to inflammation of the lungs.		✓	✓

If any of the side effects listed becomes severe or troublesome symptom, or if you notice any side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

It is unlikely that you will be asked to store BLENREP yourself. It will be stored in the hospital or clinic where it is given to you.

Store in a refrigerator (2°C to 8°C) in its original package. Do not freeze. Keep out of reach and sight 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 you want more information about BLENREP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website www.gsk.ca or by calling 1-800-387-7474.

This leaflet was prepared by GlaxoSmithKline Inc.

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