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Blenrep (*belantamab mafodotin*)

An overview of Blenrep and why it is authorised in the EU

What is Blenrep and what is it used for?

Blenrep is a cancer medicine used to treat adults with multiple myeloma (a cancer of the bone marrow) when the cancer has come back (relapsed) or has not responded to treatment (refractory).

It is used together with other medicines: bortezomib and dexamethasone in people who have received at least one previous treatment; or pomalidomide and dexamethasone in people who have received at least one previous treatment including lenalidomide.

Blenrep contains the active substance belantamab mafodotin.

How is Blenrep used?

Blenrep can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in the treatment of multiple myeloma.

Blenrep is given by infusion (drip) into a vein once every three or four weeks, depending on the other medicines it is used with. Treatment should continue until the patient no longer benefits from it, or the side effects become unacceptable.

Because Blenrep could damage the cornea (the transparent layer in front of the eye that covers the pupil and iris), patients should have their eyes checked before each of the first four doses, and as needed thereafter.

For more information about using Blenrep, see the package leaflet or contact your doctor or pharmacist.

How does Blenrep work?

The active substance in Blenrep, belantamab mafodotin, consists of a monoclonal antibody (a type of protein) attached to a cytotoxic (cell-killing) molecule. The antibody attaches to a protein called B-cell maturation antigen (BCMA), which is present on the surface of abnormal immature plasma cells (myeloma cells). When Blenrep is given to the patient, the antibody attaches to BCMA on the myeloma cells and delivers the cytotoxic molecule into the cells. Once inside, the cytotoxic molecule kills the cells by interfering with their ability to divide and grow. Blenrep also stimulates the immune system

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

(the body's natural defences) to attack the myeloma cells, and these actions combined are expected to slow down progression of the disease.

What benefits of Blenrep have been shown in studies?

Two main studies showed that Blenrep is effective at delaying progression of the disease in patients with relapsed or refractory multiple myeloma who have received at least one prior treatment.

One study investigated the use of Blenrep in 494 patients whose disease came back after at least one prior treatment. The study showed that patients treated with Blenrep plus bortezomib and dexamethasone lived on average for 36.6 months without the disease getting worse, compared with 13.4 months for patients treated with daratumumab (another cancer medicine) plus bortezomib and dexamethasone.

A second ongoing study involved 302 patients whose disease came back after at least one previous treatment including lenalidomide. The study showed that patients treated with bortezomib plus pomalidomide and dexamethasone lived on average for 12.7 months without their disease getting worse; for patients treated with Blenrep plus pomalidomide and dexamethasone, this period could not be calculated because the majority of patients had not got worse during the follow-up.

What are the risks associated with Blenrep?

For the full list of side effects and restrictions with Blenrep, see the package leaflet.

The most common side effects with Blenrep (which may affect more than 2 in 10 people) include: problems in the cornea including keratopathy (damage to the cornea), reduced vision, thrombocytopenia (low levels of blood platelets), blurred vision, dry eyes, sensation of foreign body in the eyes, photophobia (abnormal sensitivity of the eyes to light), eye irritation, neutropenia (low levels of neutrophils, a type of white blood cell), anaemia (low levels of red blood cells), diarrhoea, neuropathies (nerve damage) and eye pain.

Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include pneumonia (infection of the lungs), fever, COVID-19, pneumonia due to COVID-19 and thrombocytopenia.

Why is Blenrep authorised in the EU?

Blenrep in combination with other cancer medicines was shown to delay the progression of the disease in patients with relapsed or refractory multiple myeloma who have received at least one prior treatment. The side effects of Blenrep are mostly manageable with dose modifications and close monitoring. The European Medicines Agency therefore decided that Blenrep's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Blenrep?

The company that markets Blenrep will provide educational materials to healthcare professionals to inform them that Blenrep can affect the eyes and vision. Patients who are prescribed Blenrep will also be provided with educational materials including a patient card with this information.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Blenrep have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Blenrep are continuously monitored. Side effects reported with Blenrep are carefully evaluated and any necessary action taken to protect patients.

Other information about Blenrep

Blenrep received a marketing authorisation valid throughout the EU on 23 July 2025.

Further information on Blenrep can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/blenrep-0

This overview was last updated in 07-2025.