swissmedic

Summary report on authorisation dated 13 December 2025

Blenrep® (active substance: belantamab mafodotin)

Indication extension in Switzerland: 27 August 2025

Powder for solution for infusion in combination with bortezomib and dexamethasone for the treatment of adults with relapsed or refractory multiple myeloma after at least one prior therapy.

About the medicinal product

The medicinal product Blenrep contains the active substance belantamab mafodotin and is a powder for solution for infusion.

Blenrep is used as combination therapy for the treatment of relapsed or refractory[1] multiple myeloma in adults who have received at least one prior therapy and who experienced disease progression during the last treatment. Blenrep is now authorised for this patient group in combination with medicinal products containing the active substances bortezomib and dexamethasone.

Multiple myeloma (MM) is a rare form of cancer that accounts for around 1-2% of all cancers. The frequency of new cases of MM in Switzerland is 9.6 per 100,000 inhabitants. The disease is characterised by excessive replication of plasma cells, which are a type of white blood cell. The plasma cells multiply in an uncontrolled way in the bone marrow, which often leads to bone damage.

Blenrep was first authorised by Swissmedic on 19 June 2025 in combination with pomalidomide and dexamethasone. A previous temporary authorisation granted on 20 June 2022 for Blenrep as monotherapy was withdrawn.

Mode of action

The active substance belantamab mafodotin fights cancer cells in the body by binding to a specific marker, known as the BCMA marker, on the surface of these cells.

When belantamab mafodotin binds to this marker, the active substance penetrates the cancer cell and releases a substance that inhibits cell growth and ultimately destroys

[1] In relation to cancer, refractory means that the cancer is resistant to treatment and does not recede or may even progress despite treatment.

the cell. This can help slow the progression of the disease or keep it under control.

Administration

Blenrep is a prescription-only medicine.

Blenrep is available as a powder for solution for infusion in the dosages of 70 mg and 100 mg. The usual dose is 2.5 mg per kilogram body weight, administered as an intravenous infusion every three weeks.

The treatment may be administered only by doctors with experience in treating multiple myeloma. Blenrep is supplied as a powder and is dissolved in liquid to produce a solution for infusion. This is administered as an intravenous infusion over approximately 30 minutes and independently of meals.

An ophthalmic examination is required before each administration since Blenrep can frequently lead to changes to the cornea or visual problems. If necessary, the dosage must be reduced or the treatment temporarily interrupted. The treatment may only be administered under the supervision of healthcare professionals with experience in the treatment of multiple myeloma.

Efficacy

The efficacy of Blenrep was investigated in a randomised phase III study (DREAMM-7) with 494 patients.

In the study, Blenrep in combination with bortezomib and dexamethasone was compared with a standard treatment (daratumumab, bortezomib and dexamethasone) in adults with relapsed or refractory multiple myeloma. All participants had received at least one prior therapy and experienced disease progression during or after the last treatment.

The combination with Blenrep significantly prolonged the period until their disease progressed (progression-free survival) compared to the standard treatment. Overall survival[2] was also longer, to a statistically significant extent, in the Blenrep group.

Precautions, undesirable effects, & risks

Blenrep must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects include reduced visual acuity and corneal examination findings. Since these can be serious, an ophthalmic examination is required before each treatment cycle. The Information for healthcare professionals includes a specific boxed warning to this effect. Many patients also complained of dry eyes, a foreign body sensation, sensitivity to light, eye irritation or eye pain.

Other frequent undesirable effects are changes in blood cell counts, including a low platelet count (thrombocytopenia), low white blood cell count (neutropenia) or anaemia. Other frequently observed symptoms are fatigue, diarrhoea, upper respiratory tract infections and inflammation of the lungs.

In addition, hypersensitivity reactions can occur during the infusion, possibly requiring treatment discontinuation in rare cases.

[2] The length of time that people are still alive, on average, after starting a treatment, regardless of whether the disease improves or worsens during this time.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

A great medical need for new treatment options still exists for patients with multiple myeloma, especially for those whose disease continues to progress despite prior treatment with lenalidomide and an anti-CD38 antibody.

The DREAMM-7 trial showed that patients who received Blenrep in combination with bortezomib and dexamethasone lived longer without disease progression and experienced a better overall survival than those who received the current standard therapy.

As regards tolerability, the frequently occurring, and in some cases severe, eye side effects are especially noteworthy and require regular ophthalmic examinations and possibly dose adjustments.

Taking all the risks and precautions into account, and based on the available data, the benefits of Blenrep outweigh the risks. Swissmedic has therefore authorised Blenrep in combination with bortezomib and dexamethasone in Switzerland for the treatment of relapsed or refractory multiple myeloma.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Blenrep®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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