swissmedic

Public Summary SwissPAR dated 27 September 2022

Blenrep® (active substance: belantamab mafodotin)

Temporary authorisation in Switzerland: 20 June 2022

Medicinal product (powder) for fifth-line treatment of multiple myeloma in adults.

Information on authorisation

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

Blenrep is used in the treatment of multiple myeloma in adults who have already received at least four previous treatments that were not sufficiently effective. The disease that these patients have is refractory[1] to previous treatments and progressed with the last treatment administered.

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.

In deciding whether to authorise the medicinal product Blenrep, Swissmedic took into account the assessments of the European Medicines Agency (EMA) and in some cases the US Food and Drug Administration (FDA) regarding certain aspects such as the clinical data, as well as the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator products.

www.ema.europa.eu
www.fda.gov

Since this is a rare, life-threatening disease, Blenrep has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

The medicinal product Blenrep was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely

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

submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

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 Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.