swissmedic

Public Summary SwissPAR dated 03.12.2021

Poteligeo® (active substance: mogamulizumab)

First authorisation in Switzerland: 1 September 2021

Medicinal product for second-line treatment in adults with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS).

Information on authorisation

Poteligeo, with the active substance mogamulizumab, is used for treatment in the following patients whose cancer has spread despite previous treatment:

1. Adults with relapsed (recurring) or refractory[1] mycosis fungoides (MF)
2. Adults with relapsed or refractory Sézary syndrome (SS)

Both diseases are malignant disorders of T lymphocytes (a type of white blood cell) that mainly affect the skin. Since these cancers are rare, life-threatening diseases, Poteligeo has been authorised as an orphan drug. "Orphan drug" is a designation given to important medicinal products for rare diseases.

Poteligeo was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control. In this case, Swissmedic takes into consideration the results of checks carried out by the foreign regulatory agency, provided certain requirements are fulfilled. These involve checks on the quality, efficacy and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland.

The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Poteligeo in Switzerland, Swissmedic accepted the assessment and approval decisions of the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), and has not conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the Assessment Report and the short report issued by the reference authority:
(www.ema.europa.eu) (www.fda.gov)

[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.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Poteligeo, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

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.