swissmedic

Public Summary SwissPAR dated 12 April 2023

Jaypirca® (active substance: pirtobrutinib)

Temporary authorisation in Switzerland: 30 November 2023

Film-coated tablets for third-line treatment of adults with relapsed or refractory mantle cell lymphoma (MCL).

Information on authorisation

The medicinal product Jaypirca contains the active substance pirtobrutinib.

It is used in adults with mantle cell lymphoma (MCL) when the cancer has come back (relapsed) or the previous treatment has not been effective (refractory). Patients have also received at least 2 previous cancer treatments, including an anti-CD20 antibody therapy and a Bruton's tyrosine kinase (BTK) inhibitor therapy. Also, a specific gene therapy (CAR T-cell therapy) is considered unsuitable for them.

MCL is a malignant disorder of the lymphatic system[1]. It is an incurable disease and the prognosis after treatment with chemo-immunotherapy and BTK inhibition is very poor. The mortality risk is very high and the remaining life expectancy is short. The currently available treatment options for third-line treatment of MCL are limited.

Since MCL is a rare and life-threatening disease, the medicinal product Jaypirca has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Jaypirca has been authorised by Swissmedic 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 foreign regulatory agencies, 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.

[1]Lymphatic system: The lymphatic system includes all the lymph pathways in the body plus the lymphatic organs, including the lymph nodes, the spleen, the lymphatic tissues in the gastrointestinal tract and throat, and the thymus gland.

In deciding whether to authorise Jaypirca in Switzerland, Swissmedic accepted the assessment and approval decision of the US Food and Drug Administration (FDA) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR, Swissmedic refers to the Assessment Report issued by the reference authority: www.fda.gov
The medicinal product Jaypirca has been 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 submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation without special conditions 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 Jaypirca®

Information for patients (package leaflet): Information for patients Jaypirca®

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.