swissmedic

Public Summary SwissPAR dated 23.12.2021

Qinlock® (active substance: ripretinib)

First authorisation in Switzerland: 7 October 2021

Medicinal product for second-line treatment of adults with advanced gastrointestinal stromal tumours (GIST)

Information on authorisation

Qinlock, with the active substance ripretinib, is used for treatment in adults with advanced gastrointestinal stromal tumours (GIST) whose cancer has spread despite previous treatment. Patients have already received at least three prior treatments for their GIST before receiving Qinlock.

GIST is a tumour in the stomach and/or intestinal tract or in the oesophagus. Since this is a rare, life-threatening disease, Qinlock has been authorised as an orphan drug. "Orphan drug" is a designation given to important medicinal products for rare diseases.

Qinlock 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 Qinlock in Switzerland, Swissmedic accepted parts of the assessment and approval decision of 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.fda.gov)

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Qinlock

Information for patients (package leaflet): Information for patients Qinlock

Healthcare professionals (doctors, pharmacists and others) 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.