swissmedic

Public Summary SwissPAR dated 12 February 2021

Rubraca® (active substance: rucaparib camsylate)

First authorisation in Switzerland: 26 November 2020

Anti-cancer medicine (film-coated tablets) for the maintenance treatment of ovarian, fallopian tube or peritoneal cancer.

Information on authorisation

Rubraca contains the active substance rucaparib camsylate and has been authorised in the form of a film-coated tablet in three dosage strengths in Switzerland. Rubraca is available by prescription only.

Since these cancers are rare diseases, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Rubraca 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 Rubraca in Switzerland, Swissmedic accepted the assessment and approval decision of the U.S. Food and Drug Administration (EMA), 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

At the time of publication of the Public Summary SwissPAR for Rubraca, 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.

This information is correct as at the date above. 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.