swissmedic

Public Summary SwissPAR dated 27 April 2022

Klisyri® (active substance: tirbanibulin)

First authorisation in Switzerland: 3 February 2022

Medicinal product (ointment) for the treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis on the face or scalp in adults.

Information on authorisation

Klisyri has been authorised for the treatment of adults with non-hyperkeratotic (not heavily keratinised), non-hypertrophic (flat) actinic keratosis on the face or scalp. Actinic keratosis refers to skin lesions, usually chronic damage to the horny epidermis, caused by exposure to sunlight.

In deciding whether to authorise the medicinal product Klisyri, Swissmedic took into account the assessments of the US Food and Drug Administration (FDA) and 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 product. www.fda.gov

Further information on the medicinal product

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