swissmedic

Summary report on authorisation dated 13 March 2026

AYVAKYT® (active substance: avapritinib)

Indication extension in Switzerland: 7 August 2025

Film-coated tablets for the treatment of indolent systemic mastocytosis (ISM)

About the medicinal product

AYVAKYT contains the active substance avapritinib and is administered in the form of film-coated tablets.

Swissmedic first authorised AYVAKYT on 6 July 2023 for the treatment of adults with gastrointestinal stromal tumour (GIST) that has a specific mutation (PDGFRA-D842V) and of adults with advanced systemic mastocytosis.

The present indication extension means that AYVAKYT can also be used to treat indolent systemic mastocytosis (ISM)

ISM is a rare chronic disease in which too many mast cells build up in the body and are overactive. This repeatedly causes unpleasant symptoms such as gastrointestinal problems, flushing, pain, headaches, severe fatigue, and concentration and memory issues.

Since this is a rare, life-threatening disease, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

This indication extension for AYVAKYT was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the indication extension 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.

In deciding whether to authorise this indication extension for AYVAKYT in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) and has not conducted its own scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report and summary report issued by the reference authority.

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals AYVAKYT®

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

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 Summary report on authorisation.

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.