swissmedic

Public Summary SwissPAR dated 26.10.2021

Pemazyre® (active substance: pemigatinib)

Temporary authorisation in Switzerland: 13 July 2021

Medicinal product for second-line treatment of adults with cholangiocarcinoma (bile duct cancer) whose cancer cells have an abnormal form of the FGFR2 protein

Information on authorisation

Pemazyre is approved for the treatment of adults with bile duct cancer. The treatment is used when the cancer has spread to other parts of the body or cannot be removed by surgery and treatment with other medicinal products is not effective.

Pemazyre contains the active substance pemigatinib, which belongs to a group of cancer medicines known as "tyrosine kinase inhibitors". It blocks the action of proteins in the cell, which are known as "fibroblast growth factor receptor type 1, 2 and 3" (FGFR1, FGFR2 and FGFR3) and regulate cell growth. Cancer cells may have an abnormal form of this protein. By blocking FGFR, pemigatinib prevents the growth of these types of cancer cells.

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

Pemazyre was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials 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 ordinary authorisation.

In deciding whether to authorise the medicinal product Pemazyre, Swissmedic took into account the assessments of the European Medicines Agency (EMA), 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 products.
www.ema.europa.eu
www.fda.gov

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Pemazyre

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

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.