swissmedic

Summary report on authorisation dated 29 December 2025

Pemazyre® (active substance: pemigatinib)

Indication extension in Switzerland: 24 July 2025

Tablets as monotherapy for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

About the medicinal product

Pemazyre contains the active substance pemigatinib.

It is used for the treatment of adults with myeloid/lymphoid neoplasms (MLNs), a rare form of cancer that affects certain blood cells known as myeloid and lymphatic cells, accompanied by an abnormal form of FGFR1 (fibroblast growth factor receptor 1) when the disease has returned after earlier treatment (relapsed) or has not responded to previous therapies (refractory).

Since this type of cancer is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Pemazyre was already authorised by Swissmedic on 13 July 2021 as a second-line treatment for adults with cholangiocarcinoma (bile duct cancer) whose cancer cells have an abnormal form of the FGFR2 protein.

Mode of action

Pemazyre belongs to a group of cancer drugs called "tyrosine kinase inhibitors". It blocks the effect of proteins known as "fibroblast growth factor receptor types 1, 2, and 3" (FGFR1, FGFR2, and FGFR3) in the cells; these regulate cell growth. Cancer cells can have an abnormal form of this protein. By blocking FGFR, pemigatinib can inhibit the growth of this type of cancer cell.

Administration

Pemazyre is a prescription-only medicine.

Pemazyre is taken in the form of tablets, which are available in the dosage strengths 4.5 mg, 9 mg, and 13.5 mg. The recommended dose for the treatment of myeloid/lymphoid neoplasms is 13.5 mg once daily.

Efficacy

The efficacy of Pemazyre in adult patients with myeloid/lymphatic neoplasms (MLNs) with an abnormal form of FGFR1 was investigated in the study FIGHT-203.

The 45 patients received Pemazyre either according to an intermittent (14 days on, then 7 days off) or a continual dose schedule.

The primary endpoint of the study was achieving full remission[1] (complete response, CR). The results showed a CR rate of 68.9% in the patients.

Precautions, undesirable effects, & risks

Pemazyre may not be used in those who are hypersensitive to the active substance or any of the excipients.

Caution should be exercised when taking Pemazyre, particularly in patients with elevated or low blood phosphate levels, as the medicinal product can cause hyperphosphatemia or hypophosphatemia. Blood phosphate levels must be monitored regularly during treatment.

Pemazyre can also cause serous retinal detachment (visual impairment, flashes of light, or dark spots).

The most common undesirable effects (affecting more than 10% of all patients) are hyperphosphatemia, hypophosphatemia, serous retinal detachment, diarrhoea, alopecia (excessive hair loss), changes to the nails, stomatitis (sores in or around the mouth), constipation, dry mouth, tiredness, loss of appetite, nausea, dysgeusia (taste disturbances), abdominal pain, dry eyes, arthralgia (joint pain), dry skin, anaemia, palmar-plantar erythrodysesthesia syndrome (swelling, redness, or scaling of the skin), and an increase in blood creatinine levels.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

There are currently no authorised treatment options available in Switzerland for adult patients with myeloid or lymphatic neoplasms (MLNs) with a change in fibroblast growth receptor 1 (FGFR1) that have relapsed or do not respond to standard therapies. This rare form of cancer is generally aggressive and can quickly progress to acute leukaemia. This underlines the urgent need for new, effective therapeutic approaches.

In the clinical studies, patients achieved complete remission when treated with Pemazyre. The results showed that the continuous dosing schedule was more effective than the intermittent one. In the FIGHT-203 study, the continuous schedule was used most often, and the safety profile was assessed as acceptable. The intermittent dosing schedule has therefore not been authorised.

Taking all the risks and precautions into account, and based on the available data, the benefits of Pemazyre outweigh the risks. Swissmedic has therefore authorised the indication extension for the medicinal product Pemazyre, containing the active substance pemigatinib, in Switzerland as monotherapy for the treatment of adults with relapsed or

[1] Remission: During clinical remission the symptoms of the disease subside temporarily or permanently without the disease being cured.

refractory myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement.

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 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.