

Summary report on authorisation dated 14 November 2025

Pylclari® (active substance: piflufolastat (¹⁸F))

First authorisation in Switzerland: 25 May 2025

Solution for injection for the detection of prostate-specific membrane antigen (PSMA) positive lesions with positron emission tomography (PET) in adults with prostate cancer

About the medicinal product

Pylclari is a diagnostic radiopharmaceutical containing the active substance piflufolastat (¹⁸F) and used as a solution for injection.

Pylclari is used in connection with a PET¹ scan in order to visualise certain prostate cancer cells.

These cancer cells have a specific protein known as PSMA on their surface. The active substance piflufolastat (¹⁸F), which contains radioactive fluorine-18, binds to PSMA and therefore to prostate cancer cells. Thanks to the resulting radiolabelled cancer cells, which are visualised in the PET scan, the areas in the body affected by prostate cancer can be detected.

Pylclari is used:

- When patients are initially diagnosed with aggressive (high-risk) prostate cancer, prior to initial curative therapy (e.g. surgery or radiotherapy).
- In the event of a possible recurrence of the cancer after primary treatment. This

applies if the PSA level (level of prostate-specific antigen) in the blood increases again. Pylclari helps locate the exact site of the recurrence.

In deciding whether to authorise the medicinal product Pylclari, Swissmedic took into account the assessments of the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), and the corresponding medicinal product information texts.

Since the assessment of the clinical data was based on the assessment reports of these foreign authorities, the preconditions for a full SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign reference authorities.

www.ema.europa.eu / www.fda.gov

¹ PET: Positron emission tomography (PET) is a body scan used to show metabolic activity in the tissue.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Py-lclari®](#)

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.