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Pylclari (*piflufolastat (^{18}F)*)

An overview of Pylclari and why it is authorised in the EU

What is Pylclari and what is it used for?

Pylclari is a diagnostic medicine used in adults with prostate cancer to detect prostate cancer cells with a protein called prostate-specific membrane antigen (PSMA), using the body scan known as positron-emission tomography (PET).

It is used:

- to find out whether prostate cancer has spread to lymph nodes and other tissues outside the prostate before treatment is started;
- to find out whether prostate cancer has returned in patients whose blood levels of prostate specific antigen (PSA) are increasing after previous treatment.

Pylclari contains the active substance piflufolastat (^{18}F).

How is Pylclari used?

The medicine can only be given in a designated nuclear medicine facility by trained healthcare professionals with technical expertise in using and handling nuclear medicine imaging agents.

Pylclari is given as an injection into a vein and a PET scan is done after the injection.

For more information about using Pylclari, see the package leaflet or contact your doctor or pharmacist.

How does Pylclari work?

The active substance of Pylclari, piflufolastat (^{18}F), binds to PSMA, which is found in large numbers on the surface of most prostate cancer cells. When this diagnostic medicine is given to a patient, it binds to PSMA and is taken up by the cells. Because it contains radioactive fluorine (^{18}F) it gives off radiation, which can be detected during a PET scan. Doctors can then see where in the body the cancer cells are. Pylclari does not treat prostate cancer.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Pylclari have been shown in studies?

The benefits of Pylclari were shown in three main studies.

In the first study in 385 men with prostate cancer, all patients received Pylclari and underwent a PET scan to check the location of cancer cells. After three different doctors had looked at the scan, patients with high-risk cancer then had surgery to remove their prostate.
Among the 252 patients whose prostate was removed, the results of the PET scan correctly showed the absence of cancer cells in parts of their prostate in over 96% of patients.

The second study included 208 men with suspected prostate cancer that had come back after treatment and that could not be confirmed using a standard scan. In this study, all patients received Pylclari and underwent a PET scan. The results of the PET scan showed at least one cancer lesion in 59 to 66% of patients, depending on the doctor analysing the results of the scan, and the scan correctly identified the location of the lesion in 85 to 87% of them.

The third study included 215 men with suspected prostate cancer that had returned after treatment. These patients received either Pylclari or ^{18}F-fluorocholine (another diagnostic medicine used for imaging) before they had a PET scan, and then received the other diagnostic medicine and had another PET scan up to 12 days later. The PET scans revealed prostate cancer in 58% of these patients after they were given Pylclari, compared with 40% after patients had received the other diagnostic medicine.

What are the risks associated with Pylclari?

For the full list of side effects and restrictions with Pylclari, see the package leaflet.

The most common side effects with Pylclari (which may affect more than 1 in 100 people) include headache and loss of taste (dysgeusia).

Why is Pylclari authorised in the EU?

The European Medicines Agency considered that the use of Pylclari offered improvements over existing methods for detecting prostate cancer that has not yet been treated or has returned, and for screening patients who may benefit from PSMA-targeted treatment. Pylclari's side effects were usually mild and its safety profile was considered acceptable. The Agency therefore decided that Pylclari's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Pylclari?

The company that markets Pylclari will provide medical practitioners who are expected to use this diagnostic medicine with educational materials to support interpretation of PET scans.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pylclari have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Pylclari are continuously monitored. Suspected side effects reported with Pylclari are carefully evaluated and any necessary action taken to protect patients.

Other information about Pylclari

Pylclari received a marketing authorisation valid throughout the EU on 24 July 2023.

Further information on Pylclari can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pylclari

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