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EPAR summary for the public

Axumin

fluciclovine (^{18}F)

This is a summary of the European public assessment report (EPAR) for Axumin. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Axumin.

For practical information about using Axumin, patients should read the package leaflet or contact their doctor or pharmacist.

What is Axumin and what is it used for?

Axumin is a diagnostic medicine used with a body scan to check whether or not prostate cancer has returned.

It is used specifically with the body scan known as positron-emission tomography (PET) in men whose blood test for prostate-specific antigen (PSA) indicate that the cancer may have returned.

Axumin is a 'radiopharmaceutical': it contains the active substance fluciclovine (^{18}F), which emits a small amount of radiation.

How is Axumin used?

Axumin is available as a solution for injection, which is given as a single injection into a vein around 3 to 5 minutes before the patient is to undergo a PET scan.

Axumin can only be obtained with a prescription. The PET images must be read by nuclear medicine physicians trained in interpreting PET scan images with Axumin. Patients should discuss the results of their PET scan with their doctor. For further information, see the package leaflet.



How does Axumin work?

The active substance in Axumin, fluciclovine (¹⁸F), works by entering prostate cancer cells via structures (LAT-1 and ASCT2) that are present in high numbers on the surface of these cells. Once inside the cancer cells, it emits radiation which is detected on the PET scan, enabling doctors to see where the cancer is located.

What benefits of Axumin have been shown in studies?

In a main study involving medical records from 115 men, PET scans with Axumin correctly detected cancers in 99% of all patients whose cancer had in fact returned (as confirmed by tissue sampling). When the scans from this study were looked at by another team of researchers, the scans were again shown to be able to detect cancer in most patients who had it. (87% of patients with cancer had positive scans.)

However, because some scans with Axumin were falsely positive (showing that cancer had returned when tissue sampling was negative), a positive result on its own is not enough to make a diagnosis. Depending on the person reading the scans, only 17 to 54% of patients whose tissue samples did not show cancer had a negative scan result.

All men enrolled in this study had already shown some signs that the cancer might have returned, such as increases in blood levels of PSA, a protein produced in the prostate glands. The accuracy of the scans varied depending on the PSA levels.

What are the risks associated with Axumin?

The most common side effects with Axumin (seen in between 1 and 10 patients in 100) are taste disturbances, altered sense of smell, and pain or rash at the site of injection. For the full list of side effects and restrictions reported with Axumin, see the package leaflet.

Axumin delivers a very low amount of radiation which could pose a very low risk of cancer and hereditary abnormalities.

Why is Axumin approved?

PET scans with Axumin are effective in detecting prostate cancer and can help exclude the presence of the cancer. The side effects seen with the product are mild and rare, and there are no serious safety risks. Furthermore, the risk from radiation is very low.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that Axumin's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

The company that markets Axumin will ensure that all healthcare professional expected to use this product have access to education material to reduce errors in interpreting PET scan images.

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

Other information about Axumin

The European Commission granted a marketing authorisation valid throughout the European Union for Axumin on 22 May 2017.

The full EPAR for Axumin can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Axumin, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2017.