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EPAR summary for the public

Amyvid

florbetapir (^{18}F)

This is a summary of the European public assessment report (EPAR) for Amyvid. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Amyvid.

What is Amyvid?

Amyvid is a solution for injection that contains the active substance florbetapir (^{18}F).

What is Amyvid used for?

Amyvid is for diagnostic use only. It is used for brain scans in adult patients with memory problems so that doctors can see whether or not they have significant amounts of β-amyloid plaques in the brain. β-amyloid plaques are deposits sometimes present in the brains of people with dementias (such as Alzheimer's disease, Lewy body dementia and Parkinson's disease dementia) and some elderly people with no symptoms. The type of scan used with Amyvid is called positron emission tomography (PET).

The medicine can only be obtained with a prescription.

How is Amyvid used?

Amyvid is given by injection into a vein about 30 to 50 minutes before obtaining an image from a PET scan. After the image is obtained, it is read by nuclear medicine physicians specifically trained in interpreting PET scans with Amyvid.

PET scans with Amyvid should only be requested by doctors skilled in the clinical management of patients with neurodegenerative diseases such as Alzheimer's and other dementias. Patients should discuss the results of their PET scan with their doctor.

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How does Amyvid work?

The active substance in Amyvid, florbetapir (^{18}F), is a radiopharmaceutical that emits low amounts of radiation and works by targeting and attaching to β-amyloid plaques in the brain. When it attaches to the plaques, the radiation it emits is then seen on the PET scan, enabling doctors to know whether or not significant amount of plaques are present.

A negative scan indicates sparse or no β-amyloid plaques, which means that the patient is unlikely to have Alzheimer's disease. A positive scan on its own, however, is not sufficient to make a diagnosis in patients with memory problems, as plaque deposition may be seen in patients with different types of neurodegenerative dementias as well as in elderly people with no symptoms. Doctors will therefore need to use the scans in conjunction with clinical evaluation.

How has Amyvid been studied?

The effects of Amyvid were first tested in experimental models before being studied in humans. A main study was conducted in 226 volunteers divided into two groups: a group of healthy young people and a group of patients nearing the end of their lives who had consented to autopsies when they died.

The study looked at sensitivity and specificity of the scans (how reliable they were at differentiating volunteers who had significant amounts of plaques in the brain from those who did not). 106 volunteers completed the study and were included in the results.

What benefit has Amyvid shown during the studies?

PET scans with Amyvid were shown to have high specificity and sensitivity when used for identifying which patients had significant amounts of β-amyloid plaques in the brain. The specificity of the PET scans was 100% in 47 healthy volunteers, which means that all of their scans were rated as negative after being read by experts who were not aware if the scans belonged to healthy people or to patients.

Among the patients, 59 had autopsies carried out on them to prove conclusively whether or not they had significant amounts of β-amyloid plaques in their brains. When the results of the autopsies were compared with the PET scans, the scans were shown to have a sensitivity of 92% and a specificity of 100%. This means that the PET scans were able to correctly identify as positive 92% of the patients who had significant amounts of plaques, and that all patients without significant plaques were correctly rated as negative.

What is the risk associated with Amyvid?

The most common side effect with Amyvid (seen in between 1 and 10 patients in 100) is headache. For the full list of all side effects reported with Amyvid, see the package leaflet. Amyvid delivers a very low amount of radiation with minimal risk of cancer or any hereditary abnormalities.

Amyvid must not be used in people who are hypersensitive (allergic) to florbetapir (18F) or any of the other ingredients.

Why has Amyvid been approved?

PET scans with Amyvid were shown to have high sensitivity and specificity for detecting β-amyloid plaques in the brain, with results of the scans closely reflecting what was seen at autopsy. This is regarded as a significant improvement in the diagnosis of patients with memory problems who are being evaluated for Alzheimer's disease and other neurodegenerative diseases. The Committee noted the good safety profile and non-invasive nature of the PET scans with Amyvid and concluded that

Amyvid's benefits are greater than its risks. The Committee recommended that Amyvid be given marketing authorisation.

The CHMP did, however, note that, partly due to the limited effects of current treatments for Alzheimer's disease, there is no strong evidence of an immediate improvement in the management of patients or in patient outcomes following PET scans with Amyvid. In addition, the usefulness of Amyvid in predicting the development of Alzheimer's disease in patients with memory problems or in monitoring patients' response to treatment has not been established.

What measures are being taken to ensure the safe use of Amyvid?

The company that markets Amyvid will provide access to a training course for all nuclear medicine physicians expected to use this product in the EU in order to ensure accurate and reliable reading of the PET scan images.

Other information about Amyvid

The European Commission granted a marketing authorisation valid throughout the European Union for Amyvid on 14 January 2013.

This summary was last updated in 01-2013.