



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Amyvid Florbetapir (¹⁸F)

On 18 October 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Amyvid, 1900 MBq/mL and 800 MBq/mL solution for injection, intended for Positron Emission Tomography (PET) diagnostic imaging of β -amyloid neuritic plaque density in the brain.

The active substance of Amyvid is florbetapir (¹⁸F), a diagnostic radiopharmaceutical (V09AX05) which binds to β -amyloid neuritic plaques in the brain grey matter. These are present in some neurodegenerative dementias, including Alzheimer's disease.

The benefits with Amyvid are its ability to evidence the presence of β -amyloid neuritic plaques, whose absence can help exclude the diagnosis of Alzheimer's disease. At present there is no evidence that diagnosis with Amyvid will result in improvement in management and outcome of patients with AD. It has also not been established whether the presence of β -amyloid neuritic plaques in patients with minimal cognitive impairment predicts the development of AD.

The most common side effects are headache and taste alterations (dysgeusia).

A pharmacovigilance plan for Amyvid will be implemented as part of the marketing authorisation.

The approved indication is:

This medicinal product is for diagnostic use only.

Amyvid is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of β -amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment. Amyvid should be used in conjunction with a clinical evaluation.

A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, see sections 4.4 and 5.1.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



It is proposed that a PET scan with Amyvid should be requested by physicians skilled in the clinical management of neurodegenerative disorders. Amyvid images should only be interpreted by readers trained in the interpretation of PET images with florbetapir (^{18}F).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Amyvid and therefore recommends the granting of the marketing authorisation.