EMA/481900/2016
EMEA/H/C/002557

EPAR summary for the public

Vizamyl

flutemetamol (^{18}F)

This is a summary of the European public assessment report (EPAR) for Vizamyl. 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 Vizamyl.

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

What is Vizamyl and what is it used for?

Vizamyl is a radiopharmaceutical (a medicine containing small amounts of a radioactive substance) that contains the active substance flutemetamol (^{18}F); it is for diagnostic use only.

Vizamyl is used during brain scans in 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 brain of people with memory problems caused by dementia (such as Alzheimer's disease, Lewy-body dementia and Parkinson's disease dementia) and also in the brain of some older people with no symptoms of dementia. The type of scan used with Vizamyl is called positron-emission tomography (PET).

How is Vizamyl used?

Vizamyl can only be obtained with a prescription, and PET scans with Vizamyl should only be requested by doctors experienced in the clinical management of patients with diseases such as Alzheimer's disease and other dementias. Vizamyl is available as a solution that is given by injection into a vein, about 90 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 Vizamyl. Patients should discuss the results of their PET scan with their doctor.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2016. Reproduction is authorised provided the source is acknowledged.

How does Vizamyl work?

The active substance in Vizamyl, flutemetamol (^{18}F), is a radiopharmaceutical that emits low amounts of radiation and works by targeting and attaching to β-amyloid plaques in the brain. The radiation it emits can be detected on the PET scan, enabling doctors to see whether or not significant amount of plaques are present.

If few or no β-amyloid plaques are seen in the PET scan (a negative scan), the patient is unlikely to have Alzheimer's disease. However, a positive scan on its own is not sufficient to make a diagnosis in patients with memory problems, as plaques may be seen in patients with different types of dementias as well as in older people with no symptoms. Doctors will therefore need to use the scan together with a clinical evaluation.

What benefits of Vizamyl have been shown in studies?

Vizamyl was investigated in one main study in 176 patients nearing the end of their lives who had consented to autopsies when they died, in order to prove conclusively whether or not they had significant amounts of β-amyloid plaques in their brains. The study looked at the sensitivity of the PET scans (how well scans identified patients who had significant amounts of plaques in the brain) when interpreted by skilled readers.

At the end of the study, 68 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 between 81-93%. This means that the PET scans correctly identified as positive between 81-93% of the patients who had significant amounts of plaques in their brain.

A later re-analysis looked again at data from the original 68 patients together with results from others who had died after the end of the original study, making a total of 106 patients. In this re-analysis most readers could interpret the scans with a sensitivity of around 91% (91% of patients who had plaques were identified) and a specificity of 90% (90% of patients without plaques were correctly rated as not having plaques).

What are the risks associated with Vizamyl?

The most common side effects with Vizamyl (seen in between 1 and 10 patients in 100) are flushing (reddening of the skin) and increased blood pressure. For the full list of all side effects and restrictions reported with Vizamyl, see the package leaflet. Vizamyl delivers a very low amount of radiation which poses a very low risk of cancer or any hereditary abnormalities.

Why is Vizamyl approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Vizamyl's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee noted that PET scans with Vizamyl have a high sensitivity and specificity for detecting a significant amount of beta-amyloid plaques in the brain, and that scans closely reflect what was seen at autopsy. This is considered a significant improvement in the diagnosis of patients with memory problems who are being evaluated for Alzheimer's disease and other types of dementia. There is, however, a risk of false positive results (when patients without plaques are rated as positive), therefore Vizamyl scans should not be used on their own to diagnose dementia, but together with a clinical evaluation of the patient.

In terms of safety, Vizamyl involves exposure of the patient to small amounts of radiation, which is in the range of other approved radiopharmaceuticals, and the safety profile is therefore acceptable.

The CHMP did however note that, due to the limited effects of currently available 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 Vizamyl. In addition, the usefulness of Vizamyl 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 and effective use of Vizamyl?

A risk management plan has been developed to ensure that Vizamyl is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Vizamyl, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Vizamyl will provide access to a training course for all nuclear-medicine physicians expected to use this product in the European Union, in order to ensure accurate and reliable reading of the PET scan images.

Further information can be found in the summary of the risk management plan.

Other information about Vizamyl

The European Commission granted a marketing authorisation valid throughout the European Union for Vizamyl on 22 August 2014.

The full EPAR and risk management plan summary for Vizamyl 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 Vizamyl, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.