



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/326770/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Vizamyl

Flutemetamol (¹⁸F)

On 26 June 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vizamyl, 400 MBq/mL, solution for injection intended for the diagnosis of patients investigated for Alzheimer's disease. The applicant for this medicinal product is GE Healthcare Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Vizamyl is flutemetamol (¹⁸F), a diagnostic radiopharmaceutical agent (V09AX04) which binds to amyloid neuritic plaques in the human brain which can then be seen using by positron emitting tomography (PET).

The benefits with Vizamyl are its ability to help detect with a high accuracy the beta-amyloid deposition, and therefore contribute valuable additional information in the diagnostic process in Alzheimer's disease. The most common side effects are flushing, increased blood pressure, headache, dizziness and nausea.

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

The approved indication is: *This medicinal product is for diagnostic use only.*

Vizamyl is a radiopharmaceutical medicinal product 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. Vizamyl 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". It is proposed that

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.



Vizamyl be prescribed by clinicians experienced in the clinical management of neurodegenerative disorders.

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 Vizamyl and therefore recommends the granting of the marketing authorisation.