



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 December 2013  
EMA/CHMP/772521/2013  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Neuraceq florbetaben (<sup>18</sup>f)

On 19 December 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Neuraceq with the following therapeutic indication:

“This medicinal product is for diagnostic use only.

Neuraceq is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of  $\beta$ -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. Neuraceq 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.”

The applicant for this medicinal product is Piramal Imaging GmbH. 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 Neuraceq is florbetaben (<sup>18</sup>F), a radiopharmaceutical (V09AX) indicated for Positron Emission Tomography (PET) imaging of  $\beta$ -amyloid neuritic plaque density.

The benefits with Neuraceq are its ability to estimate beta-amyloid deposition, and therefore contribute with additional information to the clinical diagnostic process in Alzheimer’s disease. The most common side effects are injection site reactions – irritation and pain.

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

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



The approved indication is:

*"This medicinal product is for diagnostic use only.*

*Neuraceq is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of  $\beta$ -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. Neuraceq 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 Neuraceq be prescribed by physicians experienced in the clinical management of neurodegenerative disorders. Neuraceq images should only be interpreted by readers trained in the interpretation of PET images with florbetaben ( $^{18}\text{F}$ ).

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 Neuraceq and therefore recommends the granting of the marketing authorisation.