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Leqembi (*lecanemab*)

An overview of Leqembi and why it is authorised in the EU

What is Leqembi and what is it used for?

Leqembi is a medicine for treating adults with mild cognitive impairment (memory and thinking problems) and mild dementia due to Alzheimer's disease (early Alzheimer's disease). It is for use in people who have only one or no copy of *ApoE4*, a certain form of the gene for the protein apolipoprotein E, and who have amyloid beta plaques in the brain.

Leqembi contains the active substance lecanemab.

How is Leqembi used?

Leqembi can only be obtained with a prescription. It is given as an infusion (drip) into a vein once every two weeks.

Treatment should be started and supervised by a doctor experienced in the diagnosis and treatment of Alzheimer's disease, with timely access to magnetic resonance imaging (MRI). Leqembi should be given by qualified healthcare professionals trained to monitor for, recognise and manage infusion-related reactions.

The doctor should assess the patient's cognitive function and symptoms approximately every 6 months to monitor the progression of the disease. Treatment should be stopped once the patient progresses to moderate Alzheimer's disease. The doctor will also consider stopping Leqembi if the patient does not benefit from treatment.

Patients will need to have MRI scans to monitor for amyloid related imaging abnormalities (ARIA), a side effect of Leqembi seen with brain imaging that involves swelling and potential bleeding in the brain. An MRI scan will be carried out before starting treatment and before the 5th, 7th and 14th dose of Leqembi. If the patient has symptoms that suggest the presence of ARIA at any time during treatment, additional MRI scans may be carried out. The doctor may decide to interrupt treatment temporarily or stop it altogether, based on the results of the MRI scans.

For more information about using Leqembi, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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How does Leqembi work?

While the causes of Alzheimer's disease are not fully known, people with the disease have plaques in the brain made of a protein called amyloid beta, which can lead to problems with brain function. The active substance in Leqembi, lecanemab, is a monoclonal antibody (a type of protein) that attaches to amyloid beta. By attaching to amyloid beta, the medicine reduces the amyloid plaques in the brain.

What benefits of Leqembi have been shown in studies?

When compared with placebo (a dummy treatment), Leqembi was shown to slow cognitive decline in patients with early Alzheimer's disease in a main study.

The study involved 1,795 people with early Alzheimer's disease who had amyloid beta plaques in the brain and who received either Leqembi or placebo. The main measure of effectiveness was a change in symptoms after 18 months, as measured using a dementia rating scale known as CDR-SB. The CDR-SB scale is used to assess the severity of Alzheimer's disease in patients. It includes questions that help determine how much the patient's daily life has been affected by cognitive impairment. The scale ranges from 0 to 18, with higher scores indicating greater impairment.

The benefits of Leqembi were assessed in a subgroup of patients with only one or no copy of *ApoE4*, who are less likely to experience ARIA than people with two *ApoE4* copies.

In this subgroup of 1,521 patients, after 18 months of treatment, patients treated with Leqembi had a smaller increase in CDR-SB score than those who received placebo (1.22 versus 1.76). The results of other key measures were in line with those seen with the CDR-SB scale.

What are the risks associated with Leqembi?

For the full list of side effects and restrictions with Leqembi, see the package leaflet.

The most common side effects with Leqembi (which may affect more than 1 in 10 people) include infusion-related reactions, ARIA-H (haemorrhage) which involves small bleeds in the brain, and headache. Up to one in 10 people may have ARIA-E (oedema) which involves the accumulation of fluid in the brain.

Leqembi must not be used in people with bleeding disorders that are not adequately controlled and in those receiving anticoagulant treatment. Leqembi must also not be used when the pretreatment MRI scan shows previous bleeds in the brain, more than 4 microbleeds (very small chronic bleeds in the brain), superficial siderosis (a condition affecting the brain and the spinal cord that involves bleeding) or vasogenic oedema (swelling in the brain that affects the vessels), or other problems that may indicate cerebral amyloid angiopathy (build-up of amyloid proteins in arteries in the brain, causing bleeding).

Why is Leqembi authorised in the EU?

Leqembi has been shown to slow cognitive decline in patients with early Alzheimer's disease compared with placebo. The risk of ARIA is very common with Leqembi. While most people with ARIA do not experience symptoms, some may have serious ones, such as bleeds in the brain. ARIA, including its serious symptoms, is less frequent in patients with only one or no copy of *ApoE4*. The European Medicines Agency decided that in this group of patients, the risk of ARIA can be managed with appropriate risk minimisation measures.

The Agency therefore decided that Leqembi's benefits are greater than its risks in patients with mild cognitive impairment or mild dementia due to Alzheimer's disease with one or no copy of *ApoE4*, and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Leqembi?

The company that markets Leqembi will implement a controlled access programme in collaboration with national competent authorities to ensure that Leqembi is only used in the recommended patient population.

To increase awareness of ARIA and ensure early detection and treatment, the company will provide a guide and a checklist on ARIA to healthcare professionals as well as an alert card to patients. In addition, it will carry out a safety study to further characterise ARIA-E and ARIA-H and assess the effectiveness of the risk minimisation measures, based on an EU-wide registry that should include all patients treated with Leqembi.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Leqembi have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Leqembi are continuously monitored. Suspected side effects reported with Leqembi are carefully evaluated and any necessary action taken to protect patients.

Other information about Leqembi

Leqembi received a marketing authorisation valid throughout the EU on 15 April 2025.

Further information on Leqembi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/leqembi.

This overview was last updated in 04-2025.