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Kisunla (donanemab)

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

What is Kisunla and what is it used for?

Kisunla 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 people who have only one or no copy of a gene called the apolipoprotein E4 (*ApoE4*) and who have an abnormal build-up of protein deposits known as amyloid beta plaques in the brain.

Kisunla contains the active substance donanemab.

How is Kisunla used?

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

Patients will need to have a test to determine their *ApoE4* gene status. They will also have magnetic resonance imaging (MRI) scans to check for amyloid related imaging abnormalities (ARIA), a side effect of Kisunla seen with brain imaging that involves swelling and potential bleeding in the brain.

An MRI scan will be carried out in the 6 months before starting treatment and there will be additional scans before the second, third, fourth and seventh doses of Kisunla.

Treatment should only be started by a doctor experienced in diagnosing and treating Alzheimer's disease. It should also be given under supervision of a team trained to detect, monitor and manage ARIA and infusion-related reactions. Infusion-related reactions may include redness, chills, feeling sick, vomiting, sweating, headache, chest tightness, shortness of breath and changes in blood pressure. Kisunla treatment should not exceed 18 months.

For more information about using Kisunla, including about MRI scans, see the package leaflet or contact your doctor or pharmacist.

How does Kisunla work?

The active substance in Kisunla, donanemab, is a monoclonal antibody (a type of protein) that attaches to a substance in the brain called amyloid beta. In people with Alzheimer's disease, the amyloid beta accumulates in the brain as plaques which can disrupt normal brain function. By attaching to amyloid

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beta, the medicine activates microglial cells, the brain's immune cells, to clear the amyloid deposits leading to a reduction in the plaques in the brain.

What benefits of Kisunla have been shown in studies?

The company provided data from a study involving 1,736 patients with early Alzheimer's disease who had amyloid beta plaques in their brain and who received either Kisunla or placebo (a dummy treatment).

The main measure of effectiveness was a change in symptoms after 76 weeks, measured using the integrated Alzheimer's disease rating scale (iADRs). The iADRs measures cognitive and functional ability (ability to carry out daily tasks). Scores on the iADRs range from 0 to 144, with lower scores indicating worse cognitive and functional ability.

The study showed that, on average, after 18 months of treatment, the iADRs score worsened by 11 points in patients who received Kisunla and 13 points in those given placebo.

What are the risks associated with Kisunla?

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

The most common side effects with Kisunla (which may affect more than 1 in 10 people) include ARIA-H (hemorrhage), which involves small bleeds in the brain, and ARIA-E (oedema), which involves the accumulation of fluid in the brain, and headache. Some side effects can be serious. The most frequent serious side effects were ARIA-H, and ARIA-E and allergic reactions, including infusion-related reactions.

Kisunla must not be used in people with bleeding disorders that are not adequately controlled and in those receiving anticoagulant treatment. Kisunla 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).

Kisunla must not be used in people with severe disease affecting the brain's white matter or poorly controlled high blood pressure.

Kisunla must also not be used in people who cannot undergo an MRI because they have a fear of enclosed spaces (claustrophobia), have metallic implants or a metallic pacemaker in the heart.

Why is Kisunla authorised in the EU?

Kisunla slows down cognitive decline in patients with early Alzheimer's disease compared with placebo. ARIA is a common side effect and, although most patients with ARIA do not experience symptoms, some patients may have serious ones, such as bleeds in the brain. Cases of ARIA, including serious ones, are less frequent in patients with only one or no copy of ApoE4. The European Medicines Agency therefore decided that in this group of patients, the risk of ARIA can be reduced with appropriate risk minimisation measures.

The Agency concluded that Kisunla'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 Kisunla?

The company that markets Kisunla will implement a controlled access programme in collaboration with national competent authorities to ensure that Kisunla 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 for healthcare professionals as well as a card for patients to inform them about ARIA and the need to seek medical attention in case they occur.

In addition, the company will carry out a safety study to further characterise ARIA-E and ARIA-H and assess the effectiveness of the risk minimisation measures, using data from an EU registry of patients treated with Kisunla.

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

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

Other information about Kisunla

Kisunla received a marketing authorisation valid throughout the EU on 24 September 2025.

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

This overview was last updated in 10-2025.