swissmedic

Summary report on authorisation dated 14 August 2026

Kisunla® (active substance: donanemab)

Authorisation in Switzerland: 22 January 2026

Concentrate for solution for infusion for slowing the progression of Alzheimer's disease in adults who display an amyloid beta pathology typical of Alzheimer's disease and mild cognitive impairment or mild dementia

About the medicinal product

Kisunla contains the active substance donanemab.

Kisunla is used to slow the progression of Alzheimer's disease in adults. Alzheimer's disease is a common form of dementia in which memory, thinking skills and the ability to deal with everyday activities are impaired with increasing severity over time.

Treatment with Kisunla can be considered if various conditions are fulfilled.

Firstly, the adults must be in an early stage of Alzheimer's disease (mild memory impairment or mild dementia).

Secondly, potential patients must have tested positive for deposits of proteins harmful to nerve cells (called amyloid plaques) that are characteristic of Alzheimer's disease and must also fulfil genetic conditions for the ApoE ε4 gene.

Kisunla was assessed under the Access Consortium.

The Access Consortium is a joint work sharing initiative between the drug regulatory authorities in Australia (Therapeutic Goods Administration, TGA), Canada (Health Canada, HC), Singapore (Health Sciences Authority, HSA), the United Kingdom (Medicines & Healthcare products Regulatory Agency, MHRA), and Switzerland (Swissmedic). It coordinates the joint assessment of medicinal products that have been submitted for authorisation in at least two of the five countries.

The authorisation application for Kisunla was submitted to the drug regulatory authorities in Australia (TGA), Singapore (HSA) and Switzerland (Swissmedic). Each authority assessed part of the application. They then exchanged and discussed the assessments. At the end of the process, each authority makes its own decision on authorisation for its area of jurisdiction.
Swissmedic considered the foreign authorities' assessments when deciding to authorise the medicinal product.

Further information on the Access joint initiative can be found on the Swissmedic website: Access Consortium (swissmedic.ch).

Mode of action

Kisunla contains an antibody that specifically binds to amyloid plaques. This triggers an immune response in the brain that helps clear the deposits.

Administration

Kisunla is a prescription-only medicine.

Kisunla is available as a concentrate for solution for infusion. The medicinal product is administered directly into a vein as an infusion, generally at intervals of four weeks. The dose should be gradually increased to begin with (350 mg, 700 mg, 1050 mg), after which 1400 mg should be administered every four weeks.

Treatment is continued until the amyloid deposits in the brain have declined sufficiently, but for no more than 18 months. If the amyloid deposits in the brain are cleared sooner, therapy can be stopped before the end of the 18 months.

Various examinations are required before treatment starts, including genetic testing of the ApoE ε4 gene, magnetic resonance imaging (MRI) scans of the brain and specific tests to detect amyloid plaques.

Kisunla may only be used under the supervision of a doctor experienced in the treatment of Alzheimer's disease. Prompt access to an MRI scan must be guaranteed. Donanemab treatment should be administered under the supervision of a multidisciplinary team trained in the identification, monitoring and management of certain side effects (ARIA) and experienced in detecting and managing infusion related reactions.

Efficacy

The efficacy of the medicinal product was investigated in the TRAILBLAZER-ALZ 2 study, which involved 1,736 patients in an early stage of Alzheimer's disease. Participants received either Kisunla or a placebo (dummy medicinal product) for a period of 18 months.

The study demonstrated that cognitive abilities and the ability to deal with everyday activities deteriorated more slowly in patients who received Kisunla than in patients who received placebo. This effect was primarily apparent in patients with less pronounced amyloid plaques in their brain.

Precautions, undesirable effects, & risks

Kisunla must not be used in those who are hypersensitive to the active substance or any of the excipients.

Moreover, the medicinal product is not suitable for certain patients, such as those with certain changes in their brain, those at an elevated risk of brain haemorrhage or those who meet certain genetic conditions (e.g. patients who have two copies of the ApoE ε4 gene).

Patients treated with Kisunla may experience amyloid-related imaging abnormalities (ARIA) in the form of bleeding or fluid accumulation in the brain. While ARIA are frequently symptom-free, severe, life-threatening events may also occur.

The most common undesirable effects (affecting more than 1 in 10 users) are ARIA (changes in the brain: swelling or minor bleeding) and headache.

Other risks are hypersensitivity reactions, including allergic reactions, some of which may be severe.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The study showed that treatment with Kisunla can slow disease progression.

However, the benefits are offset by risks, particularly changes in the brain, some of which can be serious. For this reason, careful patient selection and close monitoring during treatment are essential.

Taking all the risks and precautions into account, and based on the available data, the benefits of Kisunla outweigh the risks. Swissmedic has therefore authorised the medicinal product Kisunla, containing the active substance donanemab, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Kisunla®

Information for patients (package leaflet): Information for patients Kisunla®
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.