Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can also report side effects directly to the authority:
Website: www.fimea.fi
Finnish Medicines Agency Fimea
Adverse reaction register
P.O. Box 55, FI-00034 FIMEA

or to the local representative of the marketing authorisation holder:
Oy Eli Lilly Finland Ab
Medical Information Service
medinfo_finland@lilly.com
Tel. 0800 140 240

If you would like to learn more about how Lilly processes personal data related to your treatment, please access https://privacynotice.lilly.com/patients-consumers or scan the attached QR code.

Important Contact Information

Your name:

_____

Doctor's name (who prescribed Kisunla):

_____

Doctor's phone number:

_____

Name of family member or caregiver (for emergency):

_____

Family member or caregiver's phone number:

_____

KISUNLA®
(donanemab)

350 mg concentrate for solution for infusion

PATIENT CARD

Important safety information

Amyloid related imaging abnormalities (ARIA)

Please keep this card with you at all times

▼ This medicinal product is subject to additional monitoring

V2.1 EU_Patient Card, Fimea approved (25/03/2026)

This Patient Card contains important information you should be aware of before, during and after stopping the treatment with Kisunla.

- Keep this Patient Card with you at all times and share it with other healthcare providers involved in your medical care or treatment, including emergency situations.
- Tell any doctor who treats you that you have been treated with Kisunla (donanemab).

Your doctor should have shared the Patient Information Leaflet (PIL) with you. If not, please request this. Please read the PIL carefully, keep it for future reference and show it to your family/caregiver.

Kisunla and the risk of brain swelling and bleeding (ARIA)

- Kisunla can cause a side effect called amyloid related imaging abnormalities (ARIA).
- Symptoms of ARIA may include:
  - headache
  - confusion
  - dizziness
  - vision changes
  - nausea
  - speech difficulty
  - weakness
  - fits (seizures)
- Your doctor will arrange magnetic resonance imaging (MRI) scans within 6 months before initiating the treatment, before your 2nd, before your 3rd, before your 4th and before your 7th dose of donanemab.

An MRI prior to the 12th dose should be performed if you carry one copy of the ApoE ε4 gene or if while on treatment you had ARIA. This is routine safety monitoring to check if you have ARIA, so please attend your MRI appointments. Additional scans can be performed at other times during treatment if your doctor thinks you need them.

If you experience any of the above-mentioned symptoms or new neurological symptoms (such as weakness, numbness, sudden personality change, poor coordination or problems with speech and language) following treatment, seek urgent medical attention and do not attempt to manage symptoms yourself.

For doctors involved in your treatment

- ARIA (detected by MRI) can cause focal neurologic deficits similar to those observed in an ischaemic stroke.
- ARIA occurs more commonly in the first 6 months of treatment with donanemab. Clinicians treating ischaemic stroke should consider whether such symptoms could be due to ARIA before giving thrombolytic therapy to the patient being treated with Kisunla (for additional details, see Kisunla Summary of Product Characteristics).