**Package leaflet: Information for the patient**

**Kisunla® 350 mg concentrate for solution for infusion**
donanemab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Kisunla is and what it is used for

Kisunla contains the active substance donanemab, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

Kisunla is used to treat the early stages of Alzheimer's disease in adults who carry one copy of a gene called apolipoprotein E4, also known as ApoE4, or in adults who do not carry this gene.

Your healthcare provider will perform testing to make sure that Kisunla is right for you.

## 2. What you need to know before you are given Kisunla

**Do not use Kisunla**
- If you are allergic to donanemab or any of the other ingredients of this medicine (listed in section 6).
- If you previously had bleeding in the brain.
- If you are receiving medicines (called anticoagulants) to prevent blood clots.

**Warnings and precautions**
Talk to your doctor, pharmacist or nurse before using Kisunla.

Amyloid Related Imaging Abnormalities (ARIA)
Kisunla can potentially cause serious side effects, including ARIA. ARIA is a side effect that usually occurs early in treatment and does not usually cause any symptoms. However, serious symptoms can occur; uncommonly ARIA can be fatal. ARIA is most commonly seen as temporary swelling in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain, and infrequently, larger areas of bleeding in the brain can occur. This may

lead to treatment being stopped. Most people with this type of swelling in the brain do not get symptoms, however some people may have symptoms, such as:

- Headache
- Confusion
- Being sick (vomiting)
- Loss of balance
- Dizziness
- Trembling
- Vision changes
- Speech disturbances
- Light-headedness and loss of consciousness
- Fits

Talk to your doctor, pharmacist or nurse before you are given Kisunla if any of the following apply to you:
- You have a bleeding disorder.
- You have Down's syndrome.

Your doctor will do magnetic resonance imaging (MRI) scans before and during your treatment with Kisunla to check you for ARIA.

Infusion-related reactions
You may experience infusion-related reactions during the infusion or immediately after the infusion. Inform your healthcare professional immediately if you experience symptoms associated with Kisunla infusion. For symptoms, see section 4 "Possible side effects".

**Children and adolescents**
Kisunla should not be used in children and adolescents under 18 years of age because Alzheimer's disease does not occur in this age group.

**Other medicines and Kisunla**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor or pharmacist before you are given Kisunla if you are taking any other medicine such as medicines to reduce blood clots from forming (antithrombotic medicines, including acetylsalicylic acid).

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The effects of Kisunla in pregnant women are not known.

**Driving and using machines**
Kisunla has no effect on the ability to drive and use machines.

**Kisunla contains sodium**
This medicine contains 46 mg sodium (main component of cooking/table salt) in each 1400 mg dose. This is equivalent to 2 % of the recommended maximum daily dietary intake of sodium for an adult. Before Kisunla is given to you, it is mixed with a solution that might contain sodium. Talk to your doctor if you are on a low salt diet.

## 3. How Kisunla will be given

Kisunla will be given to you by a healthcare professional, through a drip in the vein of your arm (intravenous infusion) over at least 30 minutes. After each infusion you will be monitored for allergic reactions for a minimum of 30 minutes.

The recommended dose of donanemab is 1400 mg. You will usually receive a dose of Kisunla once every 4 weeks. When starting the treatment with Kisunla, you will receive 700 mg once every 4 weeks

for the first three doses. Your doctor will decide how long you are treated with Kisunla. However, the total duration of treatment with Kisunla should not exceed 18 months.

**If you are given more Kisunla than you should**
This medicine will be given by a healthcare professional. If you think that you have been accidentally given too much Kisunla, please inform your doctor.

**If you forget or miss a dose of Kisunla**
If you forget or miss an appointment to receive Kisunla, make another appointment as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Immediately tell your health care professional giving you Kisunla if you notice any signs of an allergic reaction while or shortly after you are given this medicine.**

The signs may include:
- Flushing
- Chills
- Headache
- Chest tightness
- Difficulty breathing
- Muscle aches
- Changes in blood pressure

If any of these symptoms occur during infusion, the infusion should be stopped immediately.

**Very common** (may affect more than 1 in 10 people)
- Swelling in areas of the brain, with or without small spots of bleeding in or on the surface of the brain (ARIA)
- Headache

**Common** (may affect up to 1 in 10 people)
- Nausea
- Vomiting
- Infusion-related allergic reactions

**Uncommon** (may affect up to 1 in 100 people)
- Sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, and loss of consciousness

**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 this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Kisunla

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze or shake.

Keep the vial in the outer carton in order to protect from light.

Once removed from the refrigerator, Kisunla may be stored unrefrigerated for up to 3 days at room temperature 20 °C to 25 °C, prior to preparation of the diluted solution for infusion.

This medicine should not be used if it is cloudy or there are visible particles.

Kisunla should not be thrown away via wastewater or household waste. Your healthcare professional is responsible for disposing of any unused product correctly. This measure will help protect the environment.

## 6. Contents of the pack and other information

**What Kisunla contains**
- The active substance is donanemab.
- Each vial contains 350 mg donanemab in 20 ml (17.5 mg/ml)
- The other ingredients are citric acid, anhydrous; polysorbate 80; sodium citrate, dihydrate; sucrose; water for injection.

**What Kisunla looks like and contents of the pack**

Kisunla is a concentrate for solution for infusion in a clear glass vial. Its colour may vary from colourless to slightly yellow to slightly brown. Pack size of 1 vial.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

Manufacturer: Lilly France, Zone Artisanale Centre de production, 2 rue du Colonel Lilly, Fegersheim, 67640, France.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**United Kingdom**
Eli Lilly and Company Limited
Tel: + 44-(0) 1256 315000

**This leaflet was last revised in October 2024.**

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The following information is intended for healthcare professionals only:

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Each vial of donanemab is intended for single use only. Discard any unused portion.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Dilution prior to intravenous infusion
1. Prepare the solution for infusion using aseptic technique to ensure the sterility of the prepared solution.
2. Allow donanemab to equilibrate to room temperature for approximately 30 minutes before preparation.
3. Inspect the content of the vial. The concentrate should be clear, colourless to slightly yellow to slightly brown and free of visible particles. Otherwise, it should be discarded.
4. After dilution and preparation in sodium chloride 9 mg/ml (0.9 %) solution for injection (see table below), administer donanemab as an intravenous infusion:

**Preparation of donanemab**

| Kisunla Dose (mg) | Kisunla Volume (ml) | Volume of sodium chloride 9 mg/ml (0.9 %) solution for injection (ml) | Final volume of diluted solution to be infused (ml) | Final concentration of diluted solution (mg/ml)[a] |
|---|---|---|---|---|
| 700 mg | 40 ml[b] | 30 ml to 135 ml | 70 ml to 175 ml | 700 mg/175 ml (4 mg/ml) to 700 mg/70 ml (10 mg/ml) |
| 1400 mg | 80 ml[c] | 60 ml to 270 ml | 140 ml to 350 ml | 1400 mg/350 ml (4 mg/ml) to 1400 mg/140 ml (10 mg/ml) |

[a] final concentration of 4 mg/ml to 10 mg/ml
[b] 2 vials of Kisunla
[c] 4 vials of Kisunla

5. Gently invert the infusion bag to mix. Do not shake.

Administration of the diluted solution
6. The intravenous administration set (infusion line) should be connected to the prepared intravenous bag and the line should be primed. The infusion should be administered for at least 30 minutes.
7. At the end of the infusion, to ensure a full dose is administered, the infusion line should be flushed with sodium chloride 9 mg/ml (0.9 %) solution for injection. The flush should be administered at the same rate as used for Kisunla administration. The time required to flush Kisunla solution from the infusion line is in addition to the minimum 30 minutes infusion time.
8. Observe the patient post-infusion for a minimum of 30 minutes.