Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a physician's prescription only

KISUNLA
Concentrate for solution for intravenous infusion

The active ingredient and its concentration:
Each 1 mL contains 17.5 mg donanemab.
Each vial contains 350 mg donanemab in 20 mL solution.
Inactive ingredients and allergens in the preparation: see chapter 2 section "Important information about some of the ingredients of this medicine" and Chapter 6 "Additional Information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information regarding this medicine. If you have any further questions, contact your doctor or pharmacist.
This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

In addition to the leaflet, Kisunla has a patient safety information card.
This card contains important safety information that you need to know, before starting treatment and during treatment with Kisunla, and act on it. You must refer to the patient safety information card and patient leaflet before using the product. The card should be kept for further reference if necessary.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Kisunla is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer's disease (Early symptomatic Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers with confirmed amyloid pathology.

Therapeutic group: psychoanaleptics, anti-dementia drugs.

The active substance in Kisunla is donanemab. It belongs to a group of medicines called anti-dementia medicines. Donanemab is a monoclonal antibody, which acts as a protein that your body makes naturally. Donanemab recognises and binds specifically to a protein called amyloid beta, which is involved with Alzheimer's disease. By binding the amyloid beta proteins, the body's immune system is stimulated and will remove them.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are hypersensitive (allergic) to the active ingredient (donanemab) or any of the other ingredients of this medicine (listed in Chapter 6).
- you previously had bleeding in the brain or if the Magnetic Resonance Imaging (MRI) shows small spots of bleeding or fluid in the brain.
- you have an uncontrolled bleeding problem.
- you are receiving medicines (anticoagulants) to prevent blood clots.
- you have changes and damage to your brain's white matter, the pale tissue containing nerve fibres (structures like threads).
- you have uncontrolled high blood pressure.

- you cannot undergo an MRI because you live with a fear of enclosed spaces (claustrophobia), you have metal implants or you have been implanted with a metal cardiac rhythm management device (pacemaker).

Special warnings regarding the use of this medicine
Talk to your doctor, pharmacist or nurse before starting treatment with Kisunla.

Infusion-related reactions
Immediately tell the healthcare professional giving you Kisunla if you experience an allergic reaction during or shortly after receiving the infusion (drip) of Kisunla. These symptoms include redness, chills, feeling sick, vomiting, sweating, headache, chest tightness, shortness of breath and changes in blood pressure (also see Chapter 4, Side Effects).

Amyloid Related Imaging Abnormalities (ARIA)
Kisunla can cause a side effect called amyloid related imaging abnormalities (ARIA). There are two types of ARIA:

- Build-up of fluid in one or more areas of the brain (ARIA-E).
- Spots of bleeding in the brain, or on the surface of the brain (ARIA-H).

ARIA is a side effect that usually occurs early in treatment, normally in the first 24 weeks of treatment. Most people do not experience symptoms. However, cases of ARIA that resulted in serious symptoms have occurred during treatment with Kisunla, some of these cases have been fatal. These cases usually occurred within the first 12 weeks of treatment.
Symptoms of ARIA include headache, confusion, feeling sick, vomiting, loss of balance, dizziness, trembling, vision changes, speech disturbances, seizures (fits).

Tell your doctor immediately if you develop symptoms that could be signs of ARIA.

ARIA is visible on an MRI brain scan. Your doctor will arrange MRI scans within 6 months before starting the treatment, prior to the second dose, prior to the third dose, prior to the fourth dose and prior to the seventh dose. An MRI prior to the twelfth dose (at one year of treatment) should be performed if you carry one copy of the ApoE ε4 gene or if you had ARIA during treatment. Additional scans might be performed at any time during treatment if you experience symptoms of ARIA.

Depending on the results of the MRI, your doctor may stop treatment with Kisunla. This can be temporarily or permanent.

Genetic risk factors for ARIA
Some people carry a certain gene called apolipoprotein E4 (ApoE ε4). These people may be at higher risk for developing ARIA. Your doctor will test whether you are a ApoE ε4 carrier prior to starting the treatment with Kisunla.

Other risk factors for ARIA
People who had a previous bleeding in the brain may be at higher risk for developing ARIA. Your doctor will perform an MRI to check this before treatment with Kisunla can be started.

Down syndrome
Kisunla should not be used in patients with Down syndrome with associated Alzheimer's disease. Its use has not been investigated in these patients.

Children and adolescents
There is no data on the efficacy and safety of Kisunla in children and adolescents under 18 years of age. Kisunla should not be used in children and adolescents under 18 years of age.

Tests and follow-up
Before starting treatment with Kisunla, you should have had an MRI scan of your brain within the past 6 months, and you will be tested whether you are a ApoE ε4 carrier (see section "Special warnings regarding the use of this medicine").

Testing for tau
Your doctor might perform a test for tau if they consider that necessary. Tau is a certain protein in the brain that is also involved with Alzheimer's disease and from a certain level of this protein, Kisunla might work better.

Drug interactions
If you are taking or have recently taken any other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular, tell your doctor or pharmacist before you are given Kisunla if you are taking medicines (called anticoagulants) to prevent blood clots from forming. Kisunla must not be used with these medicines.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, 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. The use of Kisunla during pregnancy should be avoided.
It is unknown whether Kisunla is excreted in human milk.

Driving and using machines
Kisunla has major influence on the ability to drive and use machines if neurological deficits occur, for example visual disturbances, alteration of consciousness and seizures.

Important information about some of the ingredients of this medicine
Kisunla contains sodium
This medicine contains 46 mg sodium (main component of cooking/table salt) in each 1,400 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.

Kisunla contains polysorbate 80
This medicine contains 16 mg of polysorbate 80 in each 1,400 mg dose of medicine which is equivalent to approximately 0.23 mg/kg. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by your doctor.

Kisunla will be given to you under the supervision of a healthcare professional. Before starting treatment with Kisunla, you should have had an MRI scan of your brain within the past 6 months, and you will be tested whether you are a ApoE ε4 carrier (see Chapter 2 "Special warnings regarding the use of this medicine").

Dose
When starting treatment with Kisunla, you will receive a 350 mg dose for the first infusion, 700 mg dose for the second infusion, and 1,050 mg dose for the third infusion, once every four weeks. The dose is then increased to 1,400 mg which is given once every four weeks. Kisunla is given as 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.

Do not exceed the recommended dose.

When to stop using this medicine
Your doctor will decide how long you will be treated with Kisunla; however, the total duration of treatment with Kisunla should not exceed 18 months.

If you accidentally took a higher dose
This medicine will be given by a healthcare professional. If you think that you have accidentally been given too much Kisunla, you should contact your doctor.

If you forget to take the medicine
If you forget or miss an appointment to receive Kisunla, make another appointment as soon as possible.

Persist with the treatment as recommended by the doctor.
Even if there is an improvement in your health condition, do not discontinue treatment with this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. SIDE EFFECTS

Like all medicines, the use of Kisunla can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

Tell your doctor immediately if you experience the following side effects:

More than 1 in 10 people may experience the following side effect:
Cases of ARIA that resulted in serious symptoms, some of these cases have been fatal. Symptoms include headache, confusion, feeling sick, vomiting, loss of balance, dizziness, trembling, vision changes, speech disturbances, light-headedness, changes in consciousness, fits.

Up to 1 in 100 people may experience the following side effect:
An allergic reaction during or shortly after you are given this medicine. Symptoms include flushing, chills, feeling sick, sweating, 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.

Side effects

Very common side effects (may affect more than 1 in 10 users):
- Swelling or fluid build-up in the brain (ARIA-E)
- Bleeding or iron build-up in the brain (ARIA-H)

- Headache

Common side effects (may affect up to 1 in 10 users):
- Bleeding in the brain
- Feeling sick
- Vomiting
- Allergic reactions and other reactions due to the infusion.

Uncommon side effects (may affect up to 1 in 100 users):
- Sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, and loss of consciousness (anaphylactic reaction).

If a side effect has appeared, if one of the side effects worsens or if you suffer from a side effect not specified in the leaflet, you must consult the doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" located on the Home Page of the Ministry of Health's website (www.health.gov.il), which directs to the online form for reporting side effects, or by accessing the link: https://sideeffects.health.gov.il

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning.
Do not use this medicine after the expiry date (exp. date) which is stated on the label and the carton. The expiry date refers to the last day of that month.

Storage conditions:
Store in a refrigerator (2°C – 8°C) until time of use.
May be stored unrefrigerated for up to 3 days at room temperature (up to 25°C).
Keep the vial in the outer carton in order to protect from light.
Do not freeze or shake.

Storage conditions after dilution of the solution
Use prepared dosing solution immediately.
If not used immediately, store the Kisunla dosing solution in a refrigerator (2°C to 8°C) for up to 72 hours or for up to 12 hours at room temperature (up to 25°C) assuming dilution has taken place using aseptic techniques.
Storage times include the duration of infusion.
Do not freeze the Kisunla dosing solution.

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. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
sucrose, sodium citrate dihydrate, citric acid anhydrous, polysorbate 80, water for injection.

What the medicine looks like and contents of the pack
Kisunla concentrate for solution for infusion is a sterile, preservative-free, clear to opalescent solution in a clear glass vial. Its colour may vary from colorless to slightly yellow to slightly brown.

Pack size of 1 vial.

Registration holder's name and address:
Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411

Manufacturer's name and address:
Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana (IN) 46285, USA

Approved in January 2026.

Drug registration number at the national medicine's registry of the Ministry of Health:
181-54-38197-00

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