KISUNLA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being given KISUNLA?

KISUNLA contains the active ingredient donanemab. KISUNLA is used to treat the early stages of Alzheimer's disease in patients who carry one copy of a gene called apolipoprotein E4, also known as ApoE #4 heterozygotes, or in those who do not carry this gene. Prior to initiating KISUNLA your doctor will confirm that you have a protein known as beta-amyloid in your brain by doing a test.

For more information, see Section 1. Why am I being given KISUNLA? in the full CMI.

2. What should I know before I am given KISUNLA?

Do not use if you have ever had an allergic reaction to KISUNLA or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given KISUNLA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KISUNLA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will KISUNLA be given ?

- KISUNLA vial is diluted by your healthcare professional in a specialised centre and is given through a drip in a vein in your arm (intravenous infusion) at a dose of 350 mg for the first week, 700 mg in the second week, 1050 mg in the third week and 1400 mg every 4 weeks thereafter. Your doctor will decide when to stop KISUNLA.

- More instructions can be found in Section 4. How will KISUNLA be given? in the full CMI.

5. What should I know while using KISUNLA?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using KISUNLA. • Tell your doctor if are taking any medicine that reduces blood clots. • Tell your doctor if you are feeling unwell.
Things you should not do	• KISUNLA has been prescribed for you and should not be used by anyone else. • Do not use KISUNLA to treat any other condition, unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how KISUNLA affects you.

For more information, see Section 5. What should I know while using KISUNLA? in the full CMI.

6. Are there any side effects?

Temporary and sometimes serious swelling and/ or bleeding in areas of the brain (ARIA), headache, infusion-related allergic reactions, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNINGS

Monoclonal antibodies, like KISUNLA, target clumps of beta amyloid in the brain. These treatments can sometimes cause a side effect where swelling (ARIA-E) or bleeding (ARIA-H) occurs in the brain. This side effect is known as amyloid-related imaging abnormalities (ARIA). This can be serious or life-threatening. Before treatment your doctor will discuss possible side effects, including ARIA, and what this means for you. ARIA-E can cause specific brain problems that look like a stroke. Treatment to dissolve blood clots should be carefully considered by your doctor.

KISUNLA is not to be used if you have two copies (called being a "homozygote") of a

gene known as ApoE #4, as there is a higher chance of experiencing the side effect, ARIA. Before treatment your doctor will discuss genetic testing for ApoE #4 and what this will mean for you.

KISUNLA

Active ingredient: Donanemab

Consumer Medicine Information (CMI)

This leaflet provides important information about using KISUNLA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KISUNLA.**

Where to find information in this leaflet:

1. Why am I being given KISUNLA?

KISUNLA contains the active ingredient donanemab. Donanemab is 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 patients who carry one copy of a gene called apolipoprotein E4, also known as ApoE #4 heterozygotes, or in those who do not carry this gene.

KISUNLA belongs to a group of medicines called amyloid-targeting antibodies. This medicine works by removing from the brain a protein called beta-amyloid that is believed to cause Alzheimer’s disease to advance. Prior to initiating KISUNLA your doctor will confirm that you have this protein by doing a test.

2. What should I know before I am given KISUNLA?

Warnings

Do not use KISUNLA if:

- you have an allergy to donanemab, or any of the ingredients listed at the end of this leaflet.
- you previously had bleeding or swelling in the brain

- you have severe white matter disease, a condition where the white matter of the brain is changed or damaged.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- take any medicines for any other condition including medicines to reduce blood clots from forming (antithrombotic medicines including aspirin (acetylsalicylic acid))
- are on a low salt diet. Each KISUNLA dose is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. KISUNLA is not recommended during pregnancy. The effects of KISUNLA in pregnant women are not known

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are:

- taking any other medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.
- taking medicines to reduce blood clots from forming (antithrombotic medicines including aspirin (acetylsalicylic acid)).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KISUNLA.

4. How will KISUNLA be given?

How much and when

KISUNLA is presented as a vial containing a concentrated solution that must be diluted by a healthcare professional.

Your doses of KISUNLA will be given to you by a healthcare professional in a specialised centre through a drip in the vein of your arm (intravenous infusion) over approximately 30 minutes.

Your healthcare professional will monitor you for 30 minutes after your infusion for infusion-related reactions (see Section 5 and Section 6).

The intravenous infusion will occur every 4 weeks starting at 350 mg for the first dose, 700 mg for the second dose, 1050 mg for the third dose, followed by 1400 mg every 4 weeks. This will continue up to a maximum of 18 months.

Your doctor may change your KISUNLA dose or stop treatment based on your response to the adjusted dose.

If your KISUNLA dose is missed

If a KISUNLA dose is missed, the missed dose should be administered at the next possible opportunity by your healthcare professional. Resume KISUNLA dosing every 4 weeks thereafter.

If too much KISUNLA is given to you

KISUNLA will be given to you by a healthcare professional. If you think you have been accidentally given too much KISUNLA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using KISUNLA?

Things you should do

Remind any doctor, nurse, dentist or pharmacist you visit that you are using KISUNLA.

Call your doctor straight away if you have:

- headache, confusion, vomiting, loss of balance, dizziness, trembling, vision changes, speech disturbances, worsening of cognitive function (e.g. disorientation, communication difficulties), light-headedness and loss of consciousness and fits.

  These symptoms could be due to Amyloid Related Imaging Abnormalities (ARIA, see below).

Things you should not do

- KISUNLA has been prescribed for you and should not be used by anyone else.
- Do not use KISUNLA to treat any other condition, unless your doctor tells you to.

Amyloid Related Imaging Abnormalities (ARIA)

You should have had brain magnetic resonance imaging (MRI) within the past 6 months before you start treatment. During treatment, you will need to have additional MRI scans at specific times. These include before the second dose, before the third dose, before the fourth dose, and before the seventh dose. The purpose of these scans is to monitor for side effects that can occur with KISUNLA, particularly ARIA.

ARIA is a side effect that does not usually cause any symptoms, but 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 in larger areas in the brain. Most people with this type of swelling or bleeding in the brain do not get symptoms, however some people may have symptoms as noted under serious side effects.

ApoE #4 Genetic testing

KINSULA should not be used in patients who carry two copies of the gene ApoE #4 as this is known to increase the risk of experiencing the side effect ARIA. Your doctor will send you for genetic testing prior to treatment.

Cerebral amyloid angiopathy

This is a condition where certain proteins damage the blood vessels in the brain and may lead to bleeding and other serious issues. Your doctor may perform scans on

your brain to check if you suffer or have suffered from this condition.

Infusion related reactions

Your healthcare professional will monitor you for 30 minutes after your infusion for infusion-related reactions (see Section 6).

Driving or using machines

Be careful before you drive or use any machines or tools until you know how KISUNLA affects you.

Looking after KISUNLA

Your healthcare professional will store KISUNLA in a refrigerator between 2°C to 8°C until time of use.

Your healthcare professional will check the expiry date before use.

Getting rid of any unwanted medicine

Your healthcare professional will safely dispose of KISUNLA.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • Nausea • Vomiting **Allergy related:** • Infusion-related reaction (mild) Examples of symptoms may include flushing, chills, headache, chest tightness, difficulty breathing and muscle aches. **General** • Feeling weak or tired • Falls • Broken skin • Weight loss • Muscles feeling achy • Pain in the arms or legs	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• Dehydration • Passing out, faint **Infections** • Mild cold like symptoms, including runny or stuffy nose, mild sore throat, watery eyes, headache and feeling tired. **Nervous system related:** • Headache • Dizziness • Feeling faint **Mood related** • Depression • Trouble sleeping **Male** • Enlarge prostate, symptoms may include increased urination	

Serious side effects

Tell your doctor if you notice any unusual changes to your skin such as shiny lump that is pearly or clear, pink, red or white; and may appear scaly and dry.

Serious side effects	What to do
Serious hypersensitivity reactions: • Anaphylactic reaction Examples of symptoms may include difficulty breathing, swelling of the face, lips, mouth, tongue or throat, fast heartbeat, sweating and loss of consciousness. **Brain related:** • ARIA (amyloid related imaging abnormalities) Examples of symptoms may include headache, confusion, vomiting, loss of balance, dizziness, trembling, vision changes, speech disturbances, light-headedness, worsening of cognitive function (e.g. disorientation, communication difficulties), and loss of consciousness and fits. • Brain bleeds	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Examples of symptoms may include headache, nausea, vomiting, confusion, sudden weakness or numbness of the face, arm or leg, usually on one side, loss of consciousness, temporary loss of vision and seizures **Nervous system related:** • Superficial siderosis of the central nervous system Examples of symptoms may include hearing loss and loss of muscle control	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KISUNLA contains

Active ingredient **(main ingredient)**	**Donanemab**
Other ingredients (inactive ingredients)	Sodium citrate dihydrate Citric acid Sucrose Polysorbate 80 Water for injections

If you are allergic to any of these ingredients, tell your doctor or healthcare professional.

What KISUNLA looks like

KISUNLA 350 mg/20mL is supplied in a single use glass vial with a rubber stopper and aluminum seal. The stopper is not made with natural rubber latex (Aust R 420194).

Who distributes KISUNLA

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street, Sydney, NSW 2000

AUSTRALIA

Phone: 1800 454 559

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If you have any questions about KISUNLA, contact Eli Lilly
at 1800 454 559 (Australia) or your healthcare professional
for assistance.

This leaflet was prepared in May 2025.