

ONCE MONTHLY
kisunla[®]
(donanemab-azbt)

injection for
intravenous use
350mg/20mL

A Lilly Medicine

FDA-APPROVED

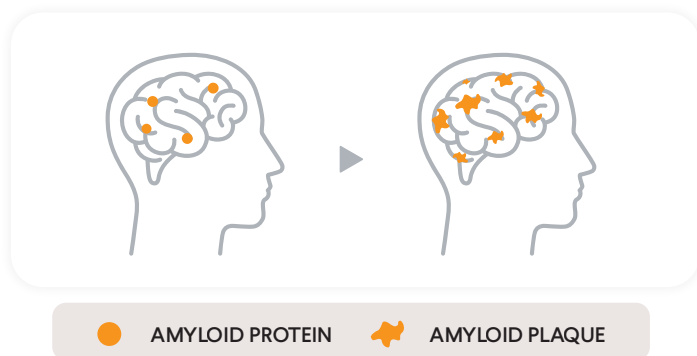


Discover what's
possible with Kisunla

Please see Indication and Safety Summary with Warnings about Amyloid-Related Imaging Abnormalities (ARIA) on [page 8](#).

Forgetting words or names more often? Losing your train of thought? It may be more than normal aging

Amyloid is a protein that your body produces naturally, but over time, it can build up and form plaques



The abnormal buildup of amyloid plaques in the brain may lead to memory and thinking issues due to Alzheimer's disease (AD).

Talking to your doctor about your memory and thinking issues can help determine if evaluation and testing is the next step for you.

SELECT SAFETY INFORMATION

Kisunla can cause **Amyloid-Related Imaging Abnormalities, or "ARIA."** ARIA is a common but serious side effect that does not usually cause any symptoms, but can be serious. ARIA can be fatal. ARIA is most commonly seen as temporary swelling in an area or areas of the brain that usually goes away over time. Some people may also have spots of bleeding on the surface of or in the brain and infrequently, larger areas of bleeding in the brain can occur.

If your doctor has determined that your memory and thinking issues are due to early symptomatic AD, Kisunla may help.



Step 1: Talk with your primary care physician (PCP) about an evaluation

This is an example of the steps someone may experience to get started on Kisunla. Individual experiences vary.

- Make an appointment to talk to your PCP about your memory and thinking issues. It may be helpful to explain specific situations when you have experienced memory and thinking issues, whether they are becoming more frequent, and what your loved ones are noticing about your symptoms. Discuss your medical and family history with your doctor as well
- Your doctor may then perform a cognitive, functional, and/or behavioral assessment
- Your doctor may run routine blood work that may help identify what is contributing to your memory and thinking issues
- Depending on the results of your initial blood work, your provider may order a blood biomarker test. This test may assess biomarkers such as P-tau217, which could help determine the likelihood of the presence of abnormal amyloid plaque buildup in your brain*
- Based on your blood work, your doctor will follow up with you to explain the results

*Must meet testing criteria. These tests are not intended to be used as a standalone diagnostic.

P-tau=phosphorylated tau.

INDICATION

Kisunla is for adults with early symptomatic Alzheimer's disease (AD), which includes mild cognitive impairment (MCI) or mild dementia stage of disease.

Please see Indication and Safety Summary with Warnings about ARIA on [page 8](#).

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Step 2: You may be referred to a specialist for further testing

- Next, your doctor may refer you to a specialist. Different types of specialists include geriatric psychiatrists, neuropsychiatrists, neurologists, and geriatricians. You may want to bring a loved one to the appointment. Wait times for seeing a specialist vary by office and geography but can sometimes take months. Explore convenient independent telehealth or in-person providers through LillyDirect
- Your specialist may review your PCP evaluation and perform tests that could include brain imaging tests (PET scans) or a cerebrospinal fluid (CSF) test to further determine if your memory and thinking issues could be due to an abnormal buildup of amyloid plaque in the brain

SELECT SAFETY INFORMATION

Kisunla can cause **Amyloid-Related Imaging Abnormalities, or “ARIA.”** Although most people do not have symptoms, some people have headache, dizziness, nausea, difficulty walking, confusion, vision changes, and seizures. **Call your healthcare provider or go to the emergency room right away if you have any of these symptoms.** You should carry information that you are receiving Kisunla, which can cause ARIA, and that ARIA symptoms can look like stroke symptoms.



Step 3: See if Kisunla treatment is right for you

- If your doctor diagnoses you with early symptomatic Alzheimer’s disease (AD), ask if Kisunla may be right for you
- Before you begin Kisunla infusions, you will undergo a baseline magnetic resonance image (MRI). Routine MRIs are one of the multiple ways your doctor will monitor you for potential side effects throughout treatment

Kisunla is a treatment for early symptomatic AD

After 18 months in a clinical study, people treated with Kisunla showed a significant slowing of decline of 22%, on average, compared with placebo

WITHIN THAT POPULATION,

PEOPLE WHO WERE EARLIER IN THEIR DISEASE PROGRESSION HAD EVEN BETTER RESULTS



The study population had varying levels of tau, a protein in the brain associated with AD. A higher amount of this protein is thought to be a factor in determining how far along a person is in the disease progression.

Please see Indication and Safety Summary with Warnings about ARIA on [page 8](#).

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Take action with Kisunla, an anti-amyloid treatment that can slow the progression of early symptomatic AD

Kisunla targets and reduces amyloid plaques in people with early symptomatic AD, which includes mild cognitive impairment (MCI) or mild dementia stage of disease.

It's possible to significantly reduce amyloid plaques associated with early symptomatic AD when taking Kisunla

In a clinical study at 18 months, people treated with Kisunla showed a significant reduction in amyloid plaques compared with those who were given placebo.

Kisunla can slow the progression of early symptomatic AD, which presents with memory and thinking issues

While Kisunla cannot reverse or stop existing memory and thinking issues that are due to early symptomatic AD, it can help slow the progression of the disease.

After 18 months in a clinical study, people treated with Kisunla experienced a significant slowing of decline compared with placebo.

SELECT SAFETY INFORMATION

(ARIA, continued) Kisunla can cause **Amyloid-Related Imaging Abnormalities, or "ARIA."** Some people have a genetic risk factor (homozygous apolipoprotein E ϵ 4 gene carriers) that may cause an increased risk for ARIA. Talk to your healthcare provider about testing to see if you have this risk factor.

You may be at higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming while receiving Kisunla. **Talk to your healthcare provider to see if you are on any medicines that increase this risk.**

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

Learn what to look for—signs and symptoms of AD

EARLY STAGE: MILD COGNITIVE IMPAIRMENT (MCI) OR MILD DEMENTIA



This is when Kisunla may help.

You may forget names or lose your train of thought, but can still live independently.

Kisunla is a treatment for early symptomatic AD. Talk to your doctor today about how Kisunla may help.

MIDDLE STAGE:

Support from loved ones will be important in helping you stay safe and engaged. Daily routines will be difficult to manage alone as you can be confused often and tend to wander or get lost.

LATE STAGE:

Memory and thinking issues become more severe and you will depend on others for everyday living activities, like eating, dressing, or getting around. Loved ones will often have a larger caregiving role at this time, offering daily support and care.

Kisunla is not indicated to treat middle and late stages of AD. Treatment options are available, including therapies that target symptoms such as memory, thinking, behavior, and mood.

For those with early symptomatic AD

In a clinical study over 18 months, people treated with Kisunla lowered their risk of progressing to the next stage of AD by 37% compared with those taking placebo.

While Kisunla is not a reversal or cure, it can help slow the progression of the disease.

Please see Indication and Safety Summary with Warnings about ARIA on [page 8](#).

What can you expect during treatment with Kisunla?

Kisunla is a once-monthly IV (intravenous) infusion given by a healthcare provider

Here are a few things to expect during the infusion process:



Kisunla is given via IV infusion through a needle placed in a vein in the arm once every 4 weeks



Each infusion takes around 30 minutes



After the infusion, you will need to stay at the medical center for 30 minutes or more for observation



Throughout your treatment journey, your doctor will monitor and evaluate how you are doing on treatment



Your doctor will determine how long you will be on treatment

SELECT SAFETY INFORMATION

Do not receive Kisunla if you: have serious allergic reactions to donanemab-azbt or any of the ingredients in Kisunla.

Kisunla can cause serious allergic and infusion-related reactions. Symptoms may include swelling of the face, lips, mouth, or eyelids, problems breathing, hives, chills, irritation of skin, nausea, vomiting, sweating, headache, or chest pain.

You will be monitored for at least 30 minutes after you receive Kisunla for any reaction. **Tell your healthcare provider right away if you have these symptoms or any reaction during or after a Kisunla infusion.**

Please see Indication and Safety Summary with Warnings about ARIA on [page 8](#).



Real patient, real story



“I don’t think of my Alzheimer’s every day”

See Pat’s journey on [Kisunla.com](https://www.kisunla.com)

Pat is a real patient and was compensated for her time



It's possible to stop taking Kisunla as early as 6 months

Your doctor may consider stopping your Kisunla treatment if your amyloid plaques are reduced to a minimal level

In a clinical study, 17% of people were able to stop taking Kisunla at 6 months, 47% at 12 months, and 69% at 18 months if their amyloid plaques were reduced to a predefined level.

PET scans were used to determine amyloid levels in the study. People who were able to stop treatment were switched to placebo.

The long-term clinical benefit of Kisunla after stopping treatment has not been studied.

SELECT SAFETY INFORMATION

The most common side effects of Kisunla include:

- Amyloid-related imaging abnormalities (ARIA)
- Infusion-related reactions
- Headache

Tell your healthcare provider right away if you have any side effects. These are not all of the possible side effects of Kisunla. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.** You may also report side effects to Lilly at 1-800-LillyRx (1-800-545-5979).

No notable amyloid plaque reaccumulation was detected 1 year after stopping treatment with Kisunla

In a clinical study, those who completed their treatment with Kisunla did not show any notable plaque reaccumulation after 1 year.

1 YEAR 
WITHOUT NOTABLE AMYLOID PLAQUE REACCUMULATION IS POSSIBLE

Those who had no notable amyloid plaque reaccumulation 1 year after completing treatment were part of a small subset of the overall population and were less progressed in their disease.

A separate analysis showed that low amounts of amyloid plaque may reaccumulate per year after stopping treatment. The duration of efficacy beyond 76 weeks has not been established, as there are no data to inform whether additional dosing with Kisunla may be needed for longer-term clinical benefit.

Please see Indication and Safety Summary with Warnings about ARIA on [page 8](#).

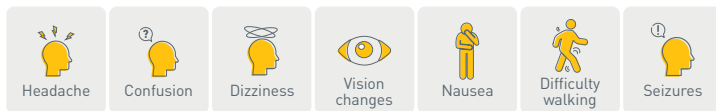
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ARIA is a possible side effect

Your doctor will monitor you closely during treatment and determine how to help manage any potential side effects

ARIA is a common side effect of Kisunla that is most commonly seen as temporary swelling of the brain that usually goes away over time, which can be serious but rarely fatal. Some people may also have spots of bleeding in or on the surface of the brain.

Although most people do not have any symptoms, some may experience headache, confusion, dizziness, vision changes, nausea, difficulty walking, and/or seizures.



Monitoring for ARIA

Some people may have an increased risk of ARIA due to a specific gene. Your healthcare provider may test for this gene. Tell your healthcare provider if you are taking medicines to reduce blood clots from forming while receiving Kisunla. Taking these medicines may increase the risk of developing bleeding in the brain.

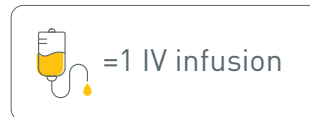
Your healthcare provider will do magnetic resonance imaging (MRI) brain scans before and during your treatment with Kisunla to check you for ARIA. You should carry information that you are receiving Kisunla, which can cause ARIA, and that ARIA symptoms can look like stroke symptoms.

These are not all the possible side effects of Kisunla.

Call your healthcare provider or go to the nearest hospital emergency room right away if you experience any side effects during treatment.

Your treatment plan

Your healthcare provider will check for ARIA with MRI scans before you start Kisunla and before your 2nd, 3rd, 4th, and 7th infusions. Your doctor may determine you need additional MRIs



Infusions are administered every 4 weeks.

Please see Indication and Safety Summary with Warnings about ARIA on [page 8](#).

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Kisunla® (kih-SUHN-lah) is used to treat adults with early symptomatic Alzheimer's disease (AD), which includes mild cognitive impairment (MCI) or mild dementia stage of disease.

Warnings - Kisunla can cause Amyloid-Related Imaging Abnormalities or "ARIA." This is a common side effect that does not usually cause any symptoms, but serious symptoms can occur. ARIA can be fatal.

ARIA is most commonly seen as temporary swelling in an area or areas of the brain that usually goes away over time. Some people may also have spots of bleeding on the surface of or in the brain and infrequently, larger areas of bleeding in the brain can occur. Although most people do not have symptoms, some people have: headache, confusion, dizziness, vision changes, nausea, difficulty walking, and/or seizures.

Some people have a genetic risk factor (homozygous apolipoprotein E ε4 gene carriers) that may cause an increased risk for ARIA. Talk to your healthcare provider about testing to see if you have this risk factor.

You may be at higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming (antithrombotic medicines) while receiving Kisunla. **Talk to your healthcare provider to see if you are on any medicines that increase this risk.**

Your healthcare provider will do magnetic resonance imaging (MRI) brain scans before and during your treatment with Kisunla to check you for ARIA. You should carry information that you are receiving Kisunla, which can cause ARIA, and that ARIA symptoms can look like stroke symptoms. **Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.**

There are registries that collect information on treatments for Alzheimer's disease. Your healthcare provider can help you become enrolled in these registries.

Warnings - Kisunla can cause serious allergic and infusion-related reactions. Do not receive Kisunla if you have serious allergic reactions to donanemab-azbt or any of the ingredients in Kisunla. Symptoms may include swelling of the face, lips, mouth, or eyelids, problems breathing, hives, chills, irritation of skin, nausea, vomiting, sweating, headache, or chest pain.

You will be monitored for at least 30 minutes after you receive Kisunla for any reaction. **Tell your healthcare provider right away if you have these symptoms or any reaction during or after a Kisunla infusion.**

Other common side effects

- Headache

Tell your healthcare provider right away if you have any side effects. These are not all of the possible side effects of Kisunla. **You can report side effects at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Before you receive Kisunla, tell your healthcare provider:

- About all medicines you take, including prescription and over-the-counter medicines, as well as vitamins and herbal supplements. Especially tell your healthcare provider if you have medicines to reduce blood clots from forming (antithrombotic medicines, including aspirin).
- About all of your medical conditions including if you are pregnant, breastfeeding, or plan to become pregnant or breastfeed. Kisunla has not been studied in people who were pregnant or breastfeeding. It is not known if Kisunla could harm your unborn or breastfeeding baby.

How to receive Kisunla

Kisunla is a prescription medicine given through an intravenous (IV) infusion using a needle inserted into a vein in your arm. Kisunla is given once every 4 weeks. Each infusion will last about 30 minutes.

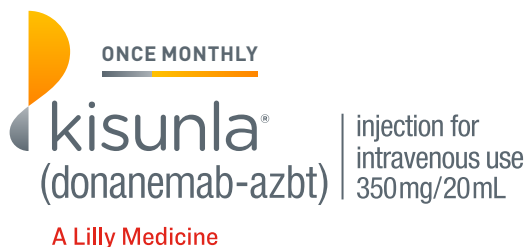
Learn more

For more information about Kisunla, call 1-800-LillyRx (1-800-545-5979) or go to kisunla.lilly.com.

This summary provides basic information about Kisunla. It does not include all information known about this medicine. Read the information given to you about Kisunla. This information does not take the place of talking with your healthcare provider. Be sure to talk to your healthcare provider about Kisunla. Your healthcare provider is the best person to help you decide if Kisunla is right for you.

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Keep moving forward on your treatment journey

Lilly Support Services[™] for Kisunla is a patient support program that's committed to offering you customized support and helping navigate your treatment experience

Lilly Support Services can partner with you to help you better understand:



Your
treatment costs



How to get started
with Kisunla



How to navigate treatment
as smoothly as possible



Call Lilly Support Services at 1-800-LillyRx (1-800-545-5979) for more information.



Visit our website to learn more about Kisunla. Hover your smartphone's camera over this QR code and click on the link that pops up on the screen.



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