Kisunla™ (donanemab-azbt) is FDA-APPROVED FOR EARLY SYMPTOMATIC ALZHEIMER'S DISEASE

kisunla™ (donanemab-azbt) | injection for IV infusion 350 mg/20 mL

Kisunla is approved for adults with early symptomatic Alzheimer's disease (AD) (mild cognitive impairment [MCI] or mild dementia stage of disease).

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.

SEE INDICATION AND SAFETY SUMMARY WITH WARNINGS FOR ARIA BELOW FOR ADDITIONAL INFORMATION.

A Closer Look at Alzheimer's Disease

In 2024, an estimated **6.9 MILLION AMERICANS AGE 65 AND OLDER** are living with Alzheimer's dementia. **By 2060, this number is projected to more than double to ~14 million**[1]

As of 2021, Alzheimer's disease was the **7TH LEADING CAUSE OF DEATH** in the United States[1]

Neuropathological evidence of Alzheimer's disease in the form of amyloid plaques may begin to accumulate in the brain **APPROXIMATELY 20 YEARS BEFORE SYMPTOMS PRESENT**[2]

Experts believe excessive amyloid plaque buildup may cause changes in the brain that make it difficult to plan or organize and remember appointments and important dates.[1-3]

Amyloid is a protein that your body produces naturally, but an excessive buildup in the brain may lead to memory and thinking issues.[1, 2]

SEE BELOW FOR INDICATION AND SAFETY SUMMARY WITH WARNINGS

Kisunla™ Is Another Treatment For Early Symptomatic Alzheimer's Disease

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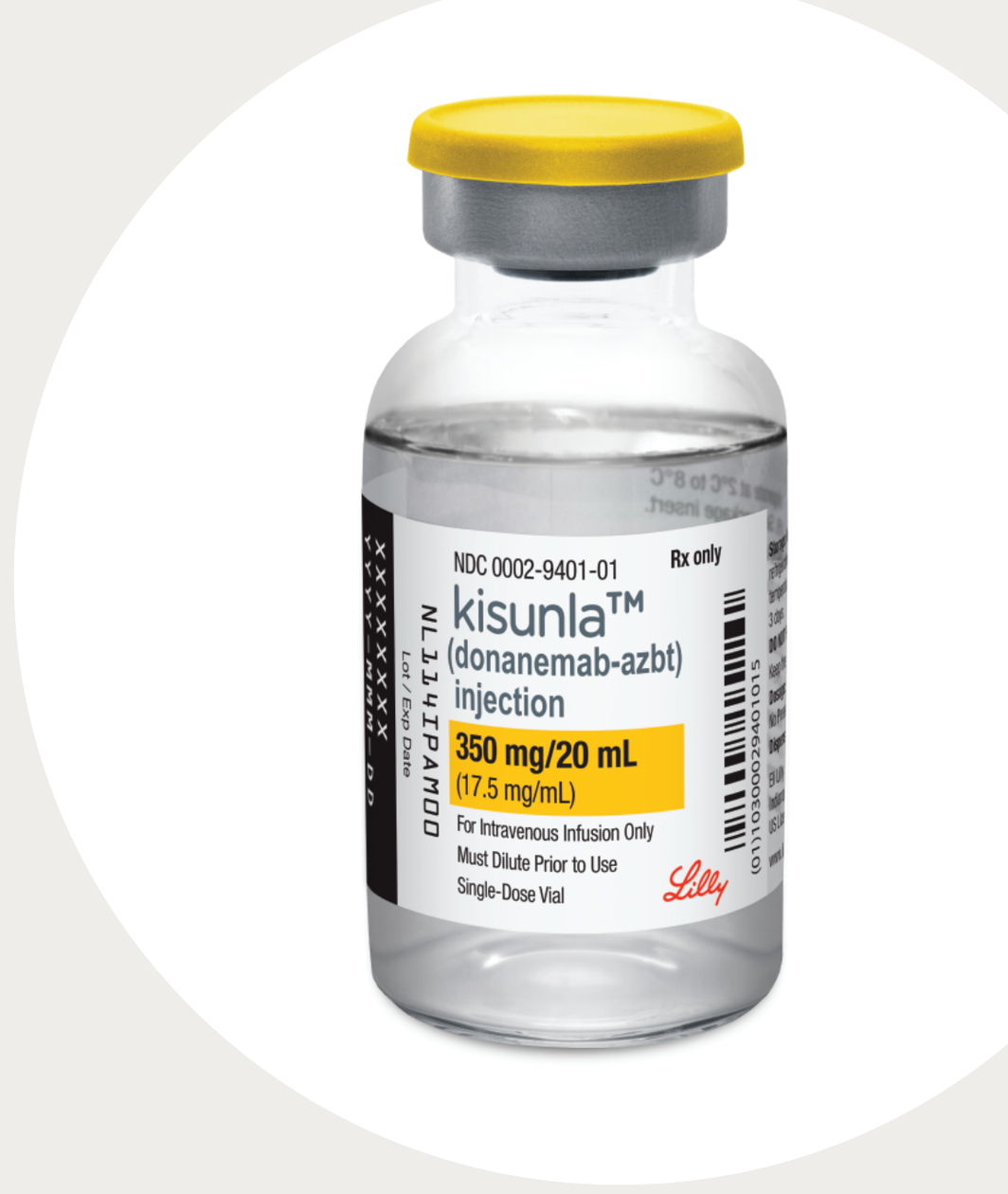
SELECT SAFETY INFORMATION

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.

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.[4]

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 imagine (MRI) brain scans before and during your treatment with Kisunla to check you for ARIA.[4]



IN THE TRAILBLAZER-ALZ 2 PHASE 3 STUDY,

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AFTER 18 MONTHS:

35%

Individuals treated with Kisunla who were less neuropathologically advanced in their disease **showed a significant slowing of decline of 35%** at 18 months compared to placebo.[5, 6]*

22%

Individuals treated with Kisunla in the combined population also **showed a significant slowing of decline of 22%** at 18 months compared to placebo.[5, 6]*

Individuals who were less neuropathologically advanced in their disease had low/medium levels of tau, another protein in the brain associated with AD. The combined population included people with low/medium or high levels of tau. A higher amount of tau is thought to be a factor in determining how far along a person is in the disease progression.[7,8]

**Measured using the integrated Alzheimer's Disease Rating Scale (iADRS), which measures memory, thinking, and daily functioning.*

KISUNLA REDUCED AMYLOID PLAQUES ON AVERAGE BY:

61% at 6 months

80% at 12 months

84% at 18 months

COMPARED TO THE START OF THE STUDY. People who took placebo had an average of <1% amyloid plaque reduction from the start of the study at 18 months.[5, 9]

The amyloid plaque reduction was measured using a positron emission tomography (PET) brain scan.[5]

SELECT SAFETY INFORMATION

Do not receive Kisunla if you: have serious allergic reactions to donanemab-azbt or any of the ingredients in Kisunla.[5]

See the *Indication and Safety Summary with Warnings* below for additional information.

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 these issues.[5]

SEE BELOW FOR INDICATION AND SAFETY SUMMARY WITH WARNINGS

A LOOK AT TRAILBLAZER-ALZ 2

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WHAT IS THE TRAILBLAZER-ALZ 2 CLINICAL TRIAL?

Kisunla was studied versus placebo in adults aged 59 to 86 years old with early symptomatic Alzheimer's disease (AD) over a period of 18 months and included people with mild cognitive impairment (MCI) or mild dementia stage of disease with confirmed amyloid plaque positivity.[5]

HOW MANY PEOPLE WERE IN TRAILBLAZER-ALZ 2?

The study enrolled 1736 people in the study. Of those, 860 people received Kisunla and 876 people received placebo.[5]

WHAT DID TRAILBLAZER-ALZ 2 MEASURE?

The clinical study was conducted to measure both changes in memory and thinking (cognition) and ability to do daily tasks (function), as well as the changes in the amount of amyloid plaques in the brain.[5]

HOW WERE RESULTS MEASURED?

The trial evaluated change of a patient's baseline score on the Integrated Alzheimer's Disease Rating Scale (iADRS).[5]

WHAT WERE SOME SAFETY CONCERNS?

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.** In the clinical trial, participants were monitored for ARIA throughout the course of the study. In addition, Kisunla can cause serious allergic and infusion-related reactions. Most common side effects are ARIA, infusion-related reactions and headache. **REFER TO THE INDICATION AND SAFETY SUMMARY WITH WARNINGS.**[5]

HOW LONG DID TREATMENT LAST?

In the clinical study, people were given Kisunla intravenously (IV) every four weeks for up to 72 weeks. The study was designed with criteria which allowed people to switch to placebo once their amyloid plaques were reduced to a pre-defined level. An amyloid PET scan was used to measure the amyloid plaque reduction. Dosing was continued or stopped in response to observed effects on amyloid imaging.[5]

WHAT IS iADRS?

The iADRS is a combination of two scores: the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog13) and the Alzheimer's Disease Cooperative Study – instrumental Activities of Daily Living (ADCS-iADL) scale. The total score ranges from 0 to 144, with lower scores reflecting worse cognitive and functional performance.[5]

SEE BELOW FOR INDICATION AND SAFETY SUMMARY WITH WARNINGS

Get Support with Lilly Support Services™

Lilly Support Services for Kisunla is a free support program committed to helping patients navigate treatment with Kisunla. The program includes offerings such as coverage determination assistance, care coordination, nurse navigator support, and customized support and resources.

Learn more about Kisunla by visiting www.Kisunla.Lilly.com.

INDICATION AND SAFETY SUMMARY WITH WARNINGS

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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
- Dizziness
- Nausea
- Difficulty walking
- Confusion
- Vision changes
- 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.

Please see full **Prescribing Information** including boxed warning for ARIA and **Medication Guide** for Kisunla.

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