

MEDICATION GUIDE
LEQEMBI® (leh-kem'-bee)
(lecanemab-irmb)
injection, for intravenous use

What is the most important information I should know about LEQEMBI?

LEQEMBI can cause serious side effects including:

- **Amyloid Related Imaging Abnormalities or “ARIA”.** ARIA is a side effect that does not usually cause any symptoms but serious symptoms can occur. ARIA can be fatal. It 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. Most people who develop ARIA do not get symptoms; however, some people may have symptoms, such as:
 - headache
 - confusion
 - dizziness
 - vision changes
 - nausea
 - difficulty walking
 - seizures

Some people have a genetic risk factor (homozygous apolipoprotein E 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 a higher risk of developing bleeding in the brain if you take medicines to reduce blood clots from forming (antithrombotic medicines) while receiving LEQEMBI.

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

You should carry information that you are receiving LEQEMBI 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. For more information, call Eisai at 888-274-2378.

What is LEQEMBI?

LEQEMBI is a prescription medicine used to treat people with Alzheimer's disease. It is not known if LEQEMBI is safe and effective in children.

Do not receive LEQEMBI if you:

- have serious allergic reactions to lecanemab-irmb or to any of the ingredients in LEQEMBI. See the end of this Medication Guide for a complete list of ingredients in LEQEMBI.

Before receiving LEQEMBI, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if LEQEMBI will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with LEQEMBI.
- are breastfeeding or plan to breastfeed. It is not known if lecanemab-irmb (the active ingredient in LEQEMBI) passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while receiving LEQEMBI.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take medicines to reduce blood clots from forming (antithrombotic medicines, including aspirin). Ask your healthcare provider for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive LEQEMBI?

- LEQEMBI is given by a healthcare provider through a needle placed in your vein (intravenous (IV) infusion) in your arm.
- Your healthcare provider will tell you how often you should receive LEQEMBI. Each infusion will last about 1 hour.

- If you miss an infusion of LEQEMBI, you should receive your next dose as soon as possible.

What are the possible side effects of LEQEMBI?

LEQEMBI can cause serious side effects, including:

- **see “What is the most important information I should know about LEQEMBI?”**
- **serious allergic reactions.** Swelling of the face, lips, mouth, or tongue, hives, or difficulty breathing have happened during a LEQEMBI infusion. Tell your healthcare provider if you have any symptoms of a serious allergic reaction during or after LEQEMBI infusion.
- **infusion-related reactions. Infusion-related reactions are a common side effect which can be serious. Tell your healthcare provider right away if you get these symptoms during an infusion of LEQEMBI:**
 - fever
 - flu-like symptoms (chills, body aches, feeling shaky, and joint pain)
 - nausea
 - vomiting
 - dizziness or lightheadedness
 - changes in your heart rate or feel like your chest is pounding
 - difficulty breathing or shortness of breath

If you have an infusion-related reaction, your healthcare provider may give you medicines before your LEQEMBI infusions to decrease your chance of having an infusion-related reaction. These medicines may include antihistamines, anti-inflammatory medicines, or steroids.

The most common side effects of LEQEMBI include:

- infusion-related reactions
- swelling in areas of the brain, with or without small spots of bleeding in or on the surface of the brain (ARIA)
- headache

These are not all the possible side effects of LEQEMBI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LEQEMBI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about LEQEMBI that is written for healthcare professionals.

What are the ingredients in LEQEMBI?

Active ingredient: lecanemab-irmb.

Inactive ingredients: arginine hydrochloride, histidine, histidine hydrochloride monohydrate, polysorbate 80, and water for injection.

Manufactured by:

Eisai Inc.

Nutley, NJ 07110

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For more information, go to www.LEQEMBI.com or call 1-888-274-2378.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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