

## 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.

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

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

### 1. Why am I receiving LEQEMBI?

LEQEMBI contains the active ingredient lecanemab. LEQEMBI 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 ε4 heterozygotes, or in those who do not carry this gene. Prior to initiating LEQEMBI 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 receiving LEQEMBI?](#) in the full CMI.

### 2. What should I know before I receive LEQEMBI?

Do not use if you have ever had an allergic reaction to lecanemab 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 receive LEQEMBI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with LEQEMBI 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 is LEQEMBI given to me?

- Your doctor will give you LEQEMBI in a specialised centre through a drip in a vein in your arm (Intravenous infusion) for about 1 hour. The amount you receive is calculated based on your weight. Your doctor will decide when to stop LEQEMBI.
- Most people receive LEQEMBI every 2 weeks.

More instructions can be found in Section [4. How is LEQEMBI given to me?](#) In the full CMI.

### 5. What should I know while being given LEQEMBI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using LEQEMBI.</li><li>• Tell your doctor if you are taking any medicine that reduces blood clots.</li><li>• If you miss an infusion call your doctor right away to arrange a new appointment.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use machines until you know how LEQEMBI affects you.</li><li>• Dizziness and confusion has been reported following administration of LEQEMBI.</li></ul>

For more information, see Section [5. What should I know while being given LEQEMBI?](#) in the full CMI.

### 6. Are there any side effects?

Like all medicines, LEQEMBI can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

Common side effects include headaches. Serious side effects include hypersensitivity to the ingredients, temporary and sometime serious swelling and/or bleeding in the brain (ARIA) and areas of bleeding in the brain.

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](http://www.tga.gov.au/reporting-problems).

## WARNINGS

Monoclonal antibodies, like LEQEMBI, 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 or "ARIA". ARIA is a side effect that does not usually cause any symptoms but serious symptoms can occur. 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, larger areas of bleeding in the brain can occur. Most people with this type of swelling in the brain do not get symptoms, however some people may have symptoms, such as:

- headache
- confusion
- dizziness
- vision changes
- nausea
- difficulty walking
- seizures

LEQEMBI is not to be used if you have two copies (called being a "homozygote") of a gene known as ApoE ε4, as there is a higher chance of experiencing the side effect, ARIA. Before treatment your doctor will discuss genetic testing for ApoE ε4 and what this will mean for you.

Some medicines can increase the risk for larger areas of bleeding in the brain in patients taking LEQEMBI. 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) scans before and during your treatment with LEQEMBI to check you for ARIA.

Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the symptoms listed above.

# LEQEMBI® (le-qem-bi)

**Active ingredient(s):** *lecanemab* (le-can-e-mab)

## Consumer Medicine Information (CMI)

This leaflet provides important information about receiving LEQEMBI. **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 LEQEMBI.**

**Where to find information in this leaflet:**

- [1. Why am I receiving LEQEMBI?](#)
- [2. What should I know before I receive LEQEMBI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is LEQEMBI given to me?](#)
- [5. What should I know while being given LEQEMBI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I receiving LEQEMBI?

**LEQEMBI contains the active ingredient lecanemab.** Lecanemab is a monoclonal antibody. Monoclonal antibodies act like natural substances made in your body and work by binding to a target protein to reduce the harmful effect of that protein. Lecanemab binds to a

protein called amyloid beta, which is involved in Alzheimer's disease.

**LEQEMBI 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 ε4 heterozygotes, or in those who do not carry this gene.** In Alzheimer's disease, clumps of amyloid beta protein form plaques in the brain. LEQEMBI works by binding to these clumps and reducing them. This slows down progression of Alzheimer's disease. Prior to initiating LEQEMBI your doctor will confirm whether you have this protein by doing a test.

## 2. What should I know before I receive LEQEMBI?

### Warnings

**Do not use LEQEMBI if:**

- you are allergic to lecanemab, or any of the ingredients listed at the end of this leaflet.
- you have severe white matter disease, a condition where the white matter of the brain is changed or damaged.
- if your Magnetic Resonance Imaging (MRI), a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed

images of the organs and tissues in your body, brain scan shows small spots of bleeding or fluid in the brain or evidence of larger bleeding in the past.

- If you are receiving medicines (called anticoagulants) to prevent blood clots.

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

#### **Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- take any medicines used to thin your blood or stop bleeding.

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. LEQEMBI is not recommended during pregnancy.

If you become pregnant while you are receiving LEQEMBI, tell your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if LEQEMBI will harm your unborn baby or if this medicine passes into breast milk.

#### **Children and adolescents**

LEQEMBI 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, including any 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)).

**Some medicines may interfere with LEQEMBI and affect how it works.**

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

### **4. How is LEQEMBI given to me?**

#### **How much you will be given**

- The recommended dose is 10 milligrams per kilogram of your body weight (mg/kg). It should be given to you every 2 weeks.

#### **When you will be given LEQEMBI**

- LEQEMBI will be given to you in a specialized centre under the supervision of a healthcare professional.
- LEQEMBI is given as a 'drip' (a needle placed in your vein) also called an intravenous (IV) infusion. Each infusion will last approximately 1 hour.

Your doctor will arrange MRI scans before your third, fifth, seventh and fourteenth doses of LEQEMBI. This is routine monitoring to check if you have ARIA (See Section [6. Are there any side effects?](#)). Additional scans can be performed at other times during treatment if your doctor thinks you need them.

- Your doctor may stop treatment temporarily, depending on your MRI results.

#### **If you miss an infusion of LEQEMBI**

If you miss an infusion of LEQEMBI, talk to your doctor to arrange to have it as soon as possible. Do not wait until your next planned infusion.

#### **When you will stop being given LEQEMBI**

Your doctor may recommend pausing or stopping treatment, depending on your clinical test results.

**If you have any further questions on the use of this medicine, ask your doctor.**

### **5. What should I know while being given LEQEMBI?**

#### **Things you should do**

- Tell any other doctors, dentists, and pharmacists who are treating you that you are being given LEQEMBI.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given LEQEMBI.

#### **Amyloid Related Imaging Abnormalities**

##### **Call your doctor straight away if you:**

- experience symptoms such as headache, confusion, dizziness, blurry vision, nausea (feeling sick), or vomiting

LEQEMBI can cause a side effect called amyloid related imaging abnormalities, or "ARIA". ARIA most commonly presents as temporary fluid in one or more regions of the brain (ARIA E), visible on a Magnetic Resonance Imaging (MRI) brain scan. The MRI uses magnetic waves to create detailed images of the soft tissues of the body. Some people may also have small spots of bleeding in the brain or on the surface of the brain (ARIA H).

Most people with ARIA do not experience symptoms. However, ARIA symptoms may occur in 2 out of 100

people. Some people may experience symptoms such as headache, confusion, dizziness, blurry vision, nausea (feeling sick), or vomiting. Most symptoms go away within 3-4 months. Tell your doctor if you experience any of these symptoms.

#### ApoE ε4 Genetic testing

LEQEMBI should not be used in patients who carry two copies of the gene ApoE ε4 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 after your infusion for infusion-related reactions.

#### Driving or using machines

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

Some patients may experience symptoms such as dizziness or confusion while being given LEQEMBI.

### 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
<b>Signs and symptoms of brain related problems:</b> <ul style="list-style-type: none"> <li>headache</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
<b>Signs and symptoms of heart related problems:</b> <ul style="list-style-type: none"> <li>Abnormal heart rhythm (atrial fibrillation).</li> </ul>	
Signs of this can include irregular heartbeat (racing or fluttering in your chest), chest pain, shortness of breath, dizziness or feeling faint, tiredness, or finding it harder to	

exercise.	
<b>Signs and symptoms of skin and subcutaneous tissue related problems:</b> <ul style="list-style-type: none"> <li>Rash</li> </ul>	
<b>Signs and symptoms of gastrointestinal related problems:</b> <ul style="list-style-type: none"> <li>Nausea</li> <li>Vomiting</li> </ul>	
<b>Signs and symptoms of infusion related reactions:</b> <ul style="list-style-type: none"> <li>shortness of breath</li> <li>itching or rash</li> <li>dizziness</li> <li>fever</li> <li>flu-like symptoms such as chills, body aches, feeling shaky and joint pain</li> <li>feeling sick (nausea)</li> <li>being sick (vomiting)</li> <li>low blood pressure</li> <li>high blood pressure</li> <li>low oxygen in your blood which can cause difficulty breathing or shortness of breath</li> <li>changes in your heart rate</li> <li>feeling like your chest is pounding</li> <li>restlessness.</li> </ul>	
<b>Signs and symptoms of hypersensitivity reactions:</b> <ul style="list-style-type: none"> <li>Delayed allergic reaction</li> </ul> Signs of a delayed allergic reaction include rash, headache, runny nose and hair loss.	

#### Serious side effects

Serious side effects	What to do
<b>Signs and symptoms of hypersensitivity reactions:</b> <ul style="list-style-type: none"> <li>Allergic Reaction</li> </ul> Signs of an allergic reaction include swelling underneath the skin, difficulty breathing caused by narrowing of the airways, serious potentially life-threatening allergic reaction, rash and headache.	<b>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.</b>

**Signs and symptoms of brain related problems:**

- ARIA (Amyloid Related Imaging Abnormalities)

Some people may experience symptoms such as headache, confusion, dizziness, blurry vision, nausea (feeling sick), vomiting (being sick), or seizures (fits). Tell your doctor if you experience any of these symptoms.

- Very small areas of bleeding in the brain
- Areas of larger bleeds in the brain (known as macrohaemorrhages)
- areas of bleeding on the surface of the brain (known as superficial siderosis).

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

**Signs and symptoms of nervous system related problems:**

- Superficial siderosis of the central nervous system

Examples of symptoms may include hearing loss and loss of muscle control.

**7. Product details**

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

**What LEQEMBI contains**

<b>Active ingredient (main ingredient)</b>	<b>Lecanemab</b>
<b>Other ingredients (inactive ingredients)</b>	histidine hydrochloride monohydrate, arginine hydrochloride, polysorbate 80, and water for injections
<b>Potential allergens</b>	None

**Do not take this medicine if you are allergic to any of these ingredients.**

**What LEQEMBI looks like**

LEQEMBI is an opalescent and colourless to pale yellow concentrate for solution for infusion that comes in a glass vial.

LEQEMBI is available in packs containing 1 vial.

1 vial containing 2 mL (Aust R 409060).

1 vial containing 5 mL (Aust R 409061).

Not all packs may be marketed.

**Who distributes LEQEMBI**

Eisai Australia Pty. Ltd.

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Southbank, VIC, 3006

03 9832 9100

[medinfo\\_australia@eisai.net](mailto:medinfo_australia@eisai.net)

This leaflet was prepared in August 2025.

**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](http://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.**