**For more information, please refer to the Summary of Product Characteristics.**

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# Important Safety Information for Healthcare Providers

- Lecanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer's disease (Early Alzheimer's disease) who are apolipoprotein E ε4 (*APOE ε4*) non-carriers or heterozygotes with confirmed amyloid pathology

## Amyloid-Related Imaging Abnormalities (ARIA)

- ARIA is characterised as ARIA with oedema (ARIA-E), which can be observed on MRI as brain oedema or sulcal effusions, and ARIA with haemosiderin deposition (ARIA-H), which includes microhaemorrhage and superficial siderosis
- ARIA-H generally occurs in association with an occurrence of ARIA-E
- ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizures and status epilepticus, can occur in rare cases
- Since MRI findings of ARIA-E may resemble those of ischaemic stroke or posterior reversible encephalopathy syndrome (PRES), it is recommended to consult a radiologist to determine the appropriate imaging procedures in cases of acute neurological presentation.

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## When present, reported symptoms associated with ARIA may include:

- headache • confusion • dizziness • visual changes • nausea • gait difficulty • seizures
- focal neurological deficits
- If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed including an MRI
- ARIA management may require stopping treatment with lecanemab, depending on clinical symptoms and severity on MRI scans
- **You should contact the patient's prescribing doctor to inform them that you have seen their patient and to discuss their management including stopping lecanemab. Please see the prescribing doctor's contact details within this card**

## Intracerebral haemorrhages (ICH)

- Intracerebral haemorrhages >1 cm in diameter including fatal events have been observed in patients taking both lecanemab and anticoagulants or in patients receiving thrombolytic agents during lecanemab treatment
- Treatment with lecanemab should not be initiated in patients receiving ongoing anticoagulant therapy
- If anticoagulation needs to be commenced during therapy with lecanemab (for example incident arterial thromboses, acute pulmonary embolism or other life-threatening indications) then lecanemab should be paused. Lecanemab can be reinstated if anticoagulation is no longer medically indicated
- Use of thrombolytic agents should be avoided except for immediately life-threatening indications with no alternative management (e.g., pulmonary embolism with haemodynamic compromise) when the benefits could outweigh the risks
- The use of concomitant aspirin and other antiplatelet therapy is permitted

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**For more information, please refer to the Summary of Product Characteristics.**

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# PATIENT ALERT CARD

LEQEMBI® (lecanemab) 100 mg/mL VIAL FOR INFUSION

Important safety information on amyloid related imaging abnormalities (ARIA) and intracerebral haemorrhage (ICH)

**Please keep this card with you at all times**

LEQEMBI
(Lecanemab) 100 mg/ml vial for infusion

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

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## This card contains important safety information that you need to be aware of before starting, during and after stopping treatment with lecanemab

- Keep this card with you at all times and show this card to any doctor or healthcare professional that you see
- Tell the doctor who prescribed lecanemab if you are taking medicines that prevent blood clots (called anticoagulants). Lecanemab should not be started when you are taking these medicines
- If a doctor wants you to receive any medication to prevent blood clots or dissolve them, tell them that you are being treated with lecanemab

**Please read the Patient Information Leaflet shared by your doctor carefully.**



## Lecanemab and the risk of brain swelling and bleeding (ARIA/ICH)

- Lecanemab is used to treat mild cognitive impairment or mild dementia due to Alzheimer's disease (also known as Early Alzheimer's disease) in adults who carry one copy of a gene called apolipoprotein E4, also known as *APOE ε4*, or in adults who do not carry this gene
- Lecanemab is a monoclonal antibody which works by binding to a harmful protein called *amyloid beta*, which is involved in Alzheimer's disease. It stimulates the body's immune system to get rid of this harmful protein
- Lecanemab is given as a 'drip' (a needle placed in your vein), also called an intravenous (IV) infusion, every 2 weeks. Each infusion will last approximately 1 hour. For the first infusion, you will be observed for 2.5 hours after being given lecanemab for any signs of an infusion-related reaction
- Lecanemab can cause a side effect called amyloid related imaging abnormalities (ARIA), characterised by the build-up of fluid in one or more areas of the brain, and/or spots of bleeding in or on the surface of the brain. Rarely larger areas of bleeding occur, known as intracerebral haemorrhage (ICH)
- Your doctor will arrange in total four instead of three MRI scans which will take place before your 3rd, 5th, 7th and 14th doses of lecanemab. This is routine safety monitoring to check if you have ARIA, so please attend your MRI appointments. Additional scans can be performed at other times during treatment if your doctor thinks you need them
- In most people, ARIA does not cause symptoms and improves on its own however, some people may have symptoms, such as:
  - headache • confusion • dizziness • blurry vision • feeling sick (nausea) • difficulty walking • seizures (fits)

**If you experience any of these symptoms, contact your doctor as soon as possible or seek emergency care and do not attempt to manage symptoms yourself**



## Reporting of side effects

If you notice any side effects, contact your doctor. This includes any possible side effects not listed in the patient information leaflet which your prescribing doctor should have given you.

You can also report side effects directly to the National Pharmacovigilance Centre (NPC) - Saudi Food and Drug Authority (SFDA) and Eisai kingdom of Saudi Arabia (EKS).

**Please report any adverse event through the following:**

National Pharmacovigilance Centre (NPC) at Saudi Food and Drug Authority (SFDA):
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/

Eisai Kingdom of Saudi Arabia (EKS) – Safety and Pharmacovigilance department:
Jude Center, 4328 Salah Ad Din Al Ayyubi Rd,
4328, 8042, Riyadh
12233, building 3
Email: ME_Safety@eisai.net
Phone: +966 55 628 5221



## Important Contact Information

**Patient's name:**

**Emergency contact (name and number):**

**Prescribing doctor's name:**

**Prescribing doctor's contact details (during working hours):**

**Prescribing doctor's emergency contact number:**

**Date lecanemab started:**