



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 ϵ 4 (*APOE ϵ 4*) 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

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 withholding or permanently 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 as well as 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

For more information, please refer to the **Summary of Product Characteristics** which is available at <https://www.medicines.ie/medicines/leqembi-100-mg-ml-concentrate-for-solution-for-infusion-36562> or by scanning the QR code below



PATIENT CARD



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

Please keep this card with you at all times

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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 involved in your care
- Tell the doctor who prescribed lecanemab if you are taking medicines that prevent blood clots (called anticoagulants). Lecanemab should not be used if 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). This involves the build-up of fluid in the brain, and/or spots of bleeding in or on the surface of the brain. Rarely, people experience large areas of bleeding in the brain known as intracerebral haemorrhage (ICH)
- Your doctor will arrange four 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 it is important to attend these 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)

In a small number of people (less than 1 out of 100 people), these symptoms may be severe. If you experience any of these symptoms, contact your doctor as soon as possible or seek emergency care. Do not attempt to manage symptoms yourself

Reporting of side effects

▼ This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. This will allow for quick identification of new safety information. You can help by reporting any side effects directly via HPRC Pharmacovigilance. Website: www.hpra.ie.

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:
