PATIENT ALERT CARD

Important safety information

Amyloid related imaging abnormalities (ARIA) and intracerebral haemorrhage (ICH)

Please keep this card with you at all times

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Important Safety Information for Healthcare Providers

- Lecanemab is indicated for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E4 (ApoE4) heterozygotes or non-carriers

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 (within the first 7 doses) and is usually asymptomatic, although serious and life-threatening events, including seizures and status epilepticus, can occur in rare cases
- As MRI findings of ARIA-E may mimic an ischaemic stroke or posterior reversible encephalopathy syndrome (PRES), please consult a radiologist on the appropriate imaging procedures for acute neurological presentations

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 if indicated to detect ARIA; please consult a radiologist on the appropriate imaging procedures for patients with acute neurological presentations
- 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

- Intracerebral haemorrhages >1 cm in diameter have been observed in patients taking both lecanemab and anticoagulants, and in patients receiving thrombolytic agents during lecanemab treatment
- Additional caution should be exercised when considering the administration of anticoagulants or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient being treated with lecanemab
- 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
- Please consult the Summary of Product Characteristics for recommendations on concomitant use of antithrombotic medication because the use of anticoagulants and thrombolytics may increase the risk of bleeding in the brain

For more information, please refer to the Summary of Product Characteristics which is available at https://www.medicines.org.uk/emc/product/15908 or by scanning the QR code below.

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 it to any doctor or healthcare professional that you see
- Tell your doctor if you are taking medicines (called anticoagulants) that prevent blood clots. Lecanemab should not be used with these medicines
- Tell your doctor that you are being treated with lecanemab before you receive any medication to prevent blood clots or dissolve them

Your doctor should have shared the Patient Information Leaflet (PIL) with you. If not, please request this. Please read the PIL carefully, keep it for future reference and show it to your family/caregiver.

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

- Lecanemab can cause a side effect called amyloid related imaging abnormalities (ARIA), characterised by temporary swelling in areas of the brain, with or without small spots of bleeding in or on the surface of the brain
- Rarely larger areas of bleeding occur known as intracerebral haemorrhage (ICH). The risk of these larger bleeds is increased if you are started on medicines to reduce blood clots
- Your doctor will arrange MRI scans before your 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
- Some cases of ARIA/ICH can be serious, life-threatening or fatal
- If experienced, some people may have symptoms, such as:
  - headache • confusion • dizziness • vision changes • feeling sick (nausea) • difficulty walking • fits (seizures)

If you experience any of these or new neurological symptoms (such as weakness, numbness, sudden personality change, poor co-ordination or problems with speech and language) following treatment, seek urgent medical attention and do not attempt to manage symptoms yourself

Reporting of side effects

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Please report side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting suspected side effects, you can help provide more information on the safety of this medicine.

Important Contact Information

Patient's name:

Emergency contact (name and number):

Prescribing doctor's name:

Prescribing doctor's 24-hour contact details:

Date lecanemab started: