Patient Alert Card

kisunla® (donanemab)

A Lilly Medicine

Important safety information for patients taking Kisunla® (donanemab)

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

Please keep this card with you at all times

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▼ 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.

Information for Patients and Caregivers

- Keep this card with you or your caregiver, and share it with other healthcare providers involved in your treatment. Keep this card for one year after your final dose of donanemab
- 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
- You should inform your physician about any new medication taken during treatment, including medicines supplied by pharmacists, nurses, dentists or other physicians
- Donanemab should not be used with medicines that prevent blood clots (anticoagulants). Tell your doctor if you are taking these medicines. Additionally, tell your doctor that you are being treated with donanemab before you receive any medication to prevent blood clots or dissolve them

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

- Donanemab 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
- Infrequently, 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 2nd, 4th and 7th doses of donanemab. 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, being sick (vomiting), loss of balance, dizziness, trembling, vision changes, speech disturbances, light-headedness and loss of consciousness, or fits (seizures)**

Seek urgent medical attention if you develop any of the listed symptoms or if you experience any other new neurological symptoms (including poor co-ordination and problems with speech and language) following donanemab treatment. You or your caregiver should read the donanemab package leaflet and keep it for future reference.

Information for Healthcare Professionals

Donanemab is indicated for the treatment of mild cognitive impairment and mild dementia due to Alzheimer's disease in adult patients that are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers.

Amyloid-Related Imaging Abnormalities (ARIA)

- ARIA includes ARIA-oedema/effusions (ARIA-E; also known as cerebral vasogenic oedema), and ARIA haemorrhage/haemosiderin deposition (ARIA-H; includes cerebral microhaemorrhage and cortical superficial siderosis). ARIA can be detected by MRI
- ARIA-H generally occurs in association with an occurrence of ARIA-E
- ARIA usually occurs early in treatment (within 24 weeks of initiation of treatment) and is usually asymptomatic, although serious and life-threatening events can occur.
- 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 patients with acute neurological presentations

When present, reported symptoms associated with ARIA may include:

• headache • confusion • nausea • vomiting • unsteadiness • dizziness • tremor
• visual disturbances • speech disturbances • worsening cognitive function
• alteration of consciousness • 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 donanemab, 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 donanemab. Please see the prescribing doctor's contact details within this card

Intracerebral haemorrhage

- Intracerebral haemorrhage greater than 1 cm in diameter and fatal events of intracerebral haemorrhage have been observed in patients taking donanemab
- Additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with donanemab. 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
- If anticoagulation needs to be commenced during therapy with donanemab (for example incident arterial thromboses, acute pulmonary embolism or other life-threatening indications) then donanemab should be paused. Donanemab therapy can be reinstated if anticoagulation is no longer medically indicated
- 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 as 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/16014/smpc or by scanning the QR code.

Important contact information

Patient's name:

Emergency contact name and number (family member or caregiver):

Prescribing doctor's name:

Prescribing doctor's 24-hour contact number:

Date donanemab started: