Patient Card

kisunla® (donanemab)

A Lilly Medicine

350 mg concentrate for solution for infusion

Important Safety Information

Amyloid-Related Imaging Abnormalities (ARIA)

Please keep this card with you at all times

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▼ This medicinal product 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 directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

Adverse events and product complaints should also be reported to Lilly: please call Lilly Ireland on 01 664 0446.

If you would like to learn more about how Lilly processes personal data related to your treatment, please access https://privacynotice.lilly.com/global/ - Global Privacy Notice for Patients and Consumers | Eli Lilly and Company

This document contains important information you should be aware of before, during, and after stopping the treatment with Kisunla®▼ (donanemab)

- Keep this Patient Card with you at all times and share it with other healthcare providers involved in your medical care or treatment, including emergency situations.
- Tell any doctor who treats you that you have been treated with 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.

Kisunla®▼ (donanemab) and the risk of brain swelling and bleeding (ARIA)

- Donanemab can cause a side effect called amyloid-related imaging abnormalities (ARIA).
- Symptoms of ARIA may include:
  - headache
  - dizziness
  - nausea
  - weakness
  - confusion
  - vision changes
  - speech difficulty
  - fits (seizures)
- Your doctor will arrange magnetic resonance imaging (MRI) scans within 6 months before initiating the treatment and before your
  - second dose
  - third dose
  - fourth dose, and
  - seventh dose of donanemab.

An MRI prior to the 12th dose should be performed if you carry 1 copy of the apolipoprotein E ε4 (ApoE ε4) gene or if while on treatment you had ARIA.

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.

If you experience any of the above-mentioned symptoms or new neurological symptoms (such as weakness, numbness, sudden personality changes, poor coordination, or problems with speech and language) following treatment, seek urgent medical attention, and do not attempt to manage symptoms yourself.

For doctors involved in your treatment

- Donanemab can cause amyloid-related imaging abnormalities (ARIA).
- ARIA (detected by MRI) can cause focal neurologic deficits similar to those observed in an ischaemic stroke.
- ARIA occurs more commonly in the first 6 months of treatment with donanemab. Clinicians treating ischaemic stroke should consider whether such symptoms could be due to ARIA before giving thrombolytic therapy to the patient being treated with donanemab. (For additional details, see Kisunla Summary of Product Characteristics, Section 4.4 ARIA and Concomitant antithrombotic treatment, available from www.hpra.ie).

Important Contact Information

Your name:

Doctor's name (who prescribed Kisunla):

Doctor's phone number:

Name of family member or caregiver (for emergency):

Family member or caregiver's phone number: