Diese englischsprachige Sicherheitsinformation dient als Ergänzung zu Ihrem Kisunla®-Patientenpass, wenn Sie sich im Ausland aufhalten. Bitte tragen Sie dieses Dokument zusätzlich zu Ihrem Patientenpass stets bei sich, solange Sie sich im Ausland aufhalten, und zeigen Sie es in Notfallsituationen den behandelnden medizinischen Fachkräften vor.

Lilly
A MEDICINE COMPANY

Safety information for doctors involved in your treatment

This patient is currently being treated with Kisunla® (donanemab).

Donanemab 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 symptomatic Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers with confirmed amyloid pathology.

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

- Kisunla® can cause a side effect called amyloid-related imaging abnormalities (ARIA).
- ARIA (detected by MRI) can cause focal neurologic deficits similar to those observed in an ischaemic stroke.
- Symptoms of ARIA may include: – headache – confusion – dizziness – vision changes – nausea – speech difficulty – weakness – fits (seizures)
- The patient is advised to seek urgent medical attention, and do not attempt to manage symptoms themselves, if they 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.
- 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 Kisunla®.
- If a patient experiences symptoms suggestive of ARIA at any time during treatment, clinical evaluation should be performed including an MRI. MRI or identification of vascular occlusion can help identify that ischemic stroke rather than ARIA is the etiology, and inform use of thrombolytics or thrombectomy when appropriate.

For additional details, please see Kisunla® summary of product characteristics.

EU Summary of Product Characteristics (SmPC) for Kisunla®

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

Important Contact Information

Patient's name:
(Ihr Name)

Kisunla® treatment initiation date:
(Datum, an dem Ihre Behandlung mit Kisunla® begonnen hat)

Doctor's name (who prescribed Kisunla®):
(Name Ihres Arztes, der Kisunla® verschrieben hat)

Doctor's phone number:
(Telefonnummer Ihres Arztes inkl. Landesvorwahl)

Name of family member or caregiver (for emergency):
(Name Ihres Notfallkontakts)

Family member or caregiver's phone number:
(Telefonnummer Ihres Notfallkontakts inkl. Landesvorwahl)

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