



אפריל 2025

hvc
human health care

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

הנדון: לקמבי- LEQEMBI, lecanemab 100 mg/ml, Concentrate for solution for infusion

חברת אסאיי ישראל בע"מ (Eisai Israel Ltd.) מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון עודכן באפריל 2025, בעקבות עדכוני בטיחות.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט ~~אדום עם קו~~ ~~חוצה~~).

ההתוויות המאושרות לתכשיר בישראל:

LEQEMBI is indicated for the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות ומצורף לפרסום זה. כמו כן, ניתן לקבל העתק מודפס שלו באמצעות פנייה לבעל הרישום: אסאיי ישראל בע"מ, ת.ד. 3393 פתח תקווה, 4951600.

להלן העדכונים בעלון לרופא:

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including LEQEMBI, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events ~~rarely~~ can occur. **ARIA can be fatal**. Serious intracerebral hemorrhages > 1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy to a patient being treated with LEQEMBI [see Warnings and Precautions (5.1), Adverse Reactions (6.1)].

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5.1 Amyloid Related Imaging Abnormalities

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ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, **rarely** can occur. **ARIA can be fatal**. When present, reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time. In addition to ARIA, intracerebral hemorrhages greater than 1 cm in diameter have occurred in patients treated with LEQEMBI.

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בברכה,
אלינה ורמן, רוקחת ממונה
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