

【Therapeutic category】 Other agents affecting central nervous system

【Non-proprietary name】 Donanemab (genetical recombination)

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>ARIA more frequently occurs in the first 24 weeks of the treatment with this drug, and serious ARIA more frequently occurs in the first 12 weeks of the treatment. Patients should be monitored especially closely during these periods. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning <u>if indicated.</u></p> <p>Even if the patient has no symptoms suggestive of ARIA, MRI scanning should be performed prior to the 2nd, 4th, and 7th doses of this drug and</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>ARIA more frequently occurs in the first 24 weeks of the treatment with this drug, and serious ARIA more frequently occurs in the first 12 weeks of the treatment. Patients should be monitored especially closely during these periods. <u>Patients and their families/caregivers should be instructed to seek immediate medical attention</u> if a patient experiences symptoms suggestive of ARIA (<u>headache, confusion, nausea, vomiting, lightheadedness, dizziness, tremor, visual disturbance, language disorder, worsening of cognitive function, alteration of consciousness, seizures, etc.</u>) irrespective of the relevant periods. In such cases, clinical evaluation should be <u>promptly</u> performed, including MRI scanning <u>if ARIA is suspected.</u></p> <p>Even if the patient has no symptoms suggestive of ARIA, MRI scanning should be performed prior to the 2nd, <u>3rd</u>, 4th, and 7th doses of this drug</p>

periodically thereafter to check whether ARIA occurs or not. Since most cases of serious ARIA occur in the first 12 weeks of the treatment with this drug, it is advisable to perform MRI scanning also prior to the 3rd dose of this drug if indicated.

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