

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Medroxyprogesterone acetate (2.5 mg) (preparations without indications such as adjusting the start of controlled ovarian stimulation in assisted reproductive technology)

December 17, 2024

Therapeutic category

Estrogen and gestagen preparations

Non-proprietary name

Medroxyprogesterone acetate (2.5 mg) (preparations without indications such as adjusting the start of controlled ovarian stimulation in assisted reproductive technology)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>(N/A)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p>(N/A)</p> <p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>(N/A)</p>	<p><u>8. IMPORTANT PRECAUTIONS</u></p> <p><u>Meningioma has been reported following administration of medroxyprogesterone acetate. Attention should be paid to symptoms suggestive of meningioma, such as headache, motor paralysis, visual impairment/visual field disorder, cranial nerve paralysis, seizure, and changes in cognitive function during administration of this drug. Imaging tests should be performed if necessary. If meningioma is diagnosed, discontinuation of this drug should be considered. Cases in which meningioma shrunk after discontinuation of administration have been reported.</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p><u>Patients with meningioma or a history of the disease</u></p> <p><u>The necessity of administration of this drug should be considered taking into account the conditions of meningioma and primary diseases.</u></p> <p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p><u>An overseas epidemiological study reported a higher risk of meningioma in women receiving medroxyprogesterone acetate compared to those not receiving it (odds ratio 5.55 (95% confidence</u></p>

	<u>interval: 2.27 to 13.56</u>)).
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[Reference] Noémie R., et al.: BMJ, 2024; 384: e078078

Note: Medroxyprogesterone acetate (2.5 mg) (preparations without indications such as adjusting the start of controlled ovarian stimulation in assisted reproductive technology) is designated as a drug requiring preparation of a Drug Guide for Patients.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.