

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

Chlormadinone acetate (50 mg)

December 17, 2024

Therapeutic category

Estrogen and gestagen preparations

Non-proprietary name

Chlormadinone acetate (50 mg)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p><u>Meningioma has been reported following administration of chlormadinone 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>(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><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. IMPORTANT PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>An overseas epidemiological study reported a higher risk of meningioma in women with cumulative doses of chlormadinone</p>	<p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>An overseas epidemiological study reported a higher risk of meningioma in women with cumulative doses of chlormadinone</p>

acetate greater than 360 mg over 6 months compared to those with cumulative doses less than or equal to 360 mg (hazard ratio 4.4 (95% confidence interval: 3.4 to 5.8)). The risk increased as the cumulative doses increased.	acetate greater than 360 mg over 6 months compared to those with cumulative doses less than or equal to 360 mg (hazard ratio 4.4 (95% confidence interval: 3.4 to 5.8)). The risk increased as the cumulative doses increased. <u>In addition, an increased risk of meningioma was reported in women receiving chlormadinone acetate compared to those not receiving it (odds ratio 3.87 (95% confidence interval: 3.48 to 4.30)).</u>
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[Reference] Noémie R., et al.: BMJ, 2024; 384: e078078

Note: Chlormadinone acetate (50 mg) 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.