

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

Rabeprazole sodium/amoxicillin hydrate/clarithromycin

March 17, 2026

Therapeutic category

Other antibiotic preparations

Non-proprietary name

Rabeprazole sodium/amoxicillin hydrate/clarithromycin

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision												
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving rilpivirine hydrochloride, pimozide, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine mesilate, suvorexant, daridorexant hydrochloride, vornorexant hydrate, lomitapide mesilate, tadalafil (Adcirca), ticagrelor, ibrutinib, ivabradine hydrochloride, venetoclax (relapsed or refractory chronic lymphocytic leukaemia [including small lymphocytic lymphoma] and relapsed or refractory mantle cell lymphoma during the dose escalation phase), lurasidone hydrochloride, anamorelin hydrochloride, finerenone, isavuconazonium sulfate, voclosporin, <u>or mavacamten</u></p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <p><Clarithromycin></p> <p>(N/A)</p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving rilpivirine hydrochloride, pimozide, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine mesilate, suvorexant, daridorexant hydrochloride, vornorexant hydrate, lomitapide mesilate, tadalafil (Adcirca), ticagrelor, ibrutinib, ivabradine hydrochloride, venetoclax (relapsed or refractory chronic lymphocytic leukaemia [including small lymphocytic lymphoma] and relapsed or refractory mantle cell lymphoma during the dose escalation phase), lurasidone hydrochloride, anamorelin hydrochloride, finerenone, isavuconazonium sulfate, voclosporin, <u>mavacamten, azelnidipine, or olmesartan medoxomil/azelnidipine</u></p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <p><Clarithromycin></p> <table border="1" data-bbox="1131 1161 1989 1398"> <thead> <tr> <th data-bbox="1131 1161 1473 1259">Drugs</th> <th data-bbox="1476 1161 1760 1259">Signs, symptoms, and treatment</th> <th data-bbox="1762 1161 1989 1259">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1131 1260 1473 1305"><u>Azelnidipine</u></td> <td data-bbox="1476 1260 1760 1305"><u>The blood</u></td> <td data-bbox="1762 1260 1989 1305"><u>The CYP3A</u></td> </tr> <tr> <td data-bbox="1131 1307 1473 1351"><u>Olmesartan</u></td> <td data-bbox="1476 1307 1760 1351"><u>concentration of</u></td> <td data-bbox="1762 1307 1989 1351"><u>inhibitory activity</u></td> </tr> <tr> <td data-bbox="1131 1353 1473 1398"><u>medoxomil/azelnidipine</u></td> <td data-bbox="1476 1353 1760 1398"><u>azelnidipine may</u></td> <td data-bbox="1762 1353 1989 1398"><u>of clarithromycin</u></td> </tr> </tbody> </table>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Azelnidipine</u>	<u>The blood</u>	<u>The CYP3A</u>	<u>Olmesartan</u>	<u>concentration of</u>	<u>inhibitory activity</u>	<u>medoxomil/azelnidipine</u>	<u>azelnidipine may</u>	<u>of clarithromycin</u>
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		<u>increase, and its effects may be enhanced.</u>	<u>may suppress the metabolism of these drugs, leading to an increase in their blood concentration.</u>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.