

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

Vonoprazan fumarate/amoxicillin hydrate/clarithromycin

March 17, 2026

Therapeutic category

Other antibiotic preparations

Non-proprietary name

Vonoprazan fumarate/amoxicillin hydrate/clarithromycin

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

| Current | Revision | | | | | | | | | | | |
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| <p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving atazanavir sulfate, rilpivirine hydrochloride, pimozone, 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</u> mavacamten</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 atazanavir sulfate, rilpivirine hydrochloride, pimozone, 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, mavacamten, <u>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="1133 1209 1989 1398"> <thead> <tr> <th data-bbox="1133 1209 1473 1310">Drugs</th> <th data-bbox="1473 1209 1765 1310">Signs, symptoms, and treatment</th> <th data-bbox="1765 1209 1989 1310">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1133 1310 1473 1358"><u>Azelnidipine</u></td> <td data-bbox="1473 1310 1765 1358"><u>The blood</u></td> <td data-bbox="1765 1310 1989 1358"><u>The CYP3A</u></td> </tr> <tr> <td data-bbox="1133 1358 1473 1398"><u>Olmesartan</u></td> <td data-bbox="1473 1358 1765 1398"><u>concentration of</u></td> <td data-bbox="1765 1358 1989 1398"><u>inhibitory activity</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> |
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| | <u>medoxomil/azelnidipine</u> | <u>azelnidipine may increase, and its effects may be enhanced.</u> | <u>of clarithromycin 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.