

*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

## Olmesartan medoxomil/azelnidipine

March 17, 2026

### **Therapeutic category**

Antihypertensives

### **Non-proprietary name**

Olmesartan medoxomil/azelnidipine

### **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 the following drugs: Itraconazole, miconazole (oral dosage form, injections, agents for oral use), fluconazole, fosfluconazole, voriconazole, posaconazole, HIV protease inhibitors (preparations containing ritonavir, atazanavir sulfate, fosamprenavir calcium hydrate, preparations containing darunavir), preparations containing cobicistat, nirmatrelvir/ritonavir, ensitrelvir fumaric acid</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <p>(N/A)</p> | <p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: Itraconazole, miconazole (oral dosage form, injections, agents for oral use), fluconazole, fosfluconazole, voriconazole, posaconazole, HIV protease inhibitors (preparations containing ritonavir, atazanavir sulfate, fosamprenavir calcium hydrate, preparations containing darunavir), preparations containing cobicistat, nirmatrelvir/ritonavir, ensitrelvir fumaric acid, <u>clarithromycin, ceritinib</u></p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <table border="1" data-bbox="1133 970 1984 1318"> <thead> <tr> <th data-bbox="1133 970 1473 1075">Drugs</th> <th data-bbox="1478 970 1760 1075">Signs, symptoms, and treatment</th> <th data-bbox="1765 970 1984 1075">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1133 1078 1473 1318"> <u>Clarithromycin</u><br/> <u>Ceritinib</u> </td> <td data-bbox="1478 1078 1760 1318"> <u>The effects of azelnidipine may be enhanced.</u> </td> <td data-bbox="1765 1078 1984 1318"> <u>It is considered that these drugs inhibit CYP3A4 and that the clearance of</u> </td> </tr> </tbody> </table> |   |  | Drugs | Signs, symptoms, and treatment | Mechanism/risk factors | <u>Clarithromycin</u><br><u>Ceritinib</u> | <u>The effects of azelnidipine may be enhanced.</u> | <u>It is considered that these drugs inhibit CYP3A4 and that the clearance of</u> |
| Drugs   | Signs, symptoms, and treatment   | Mechanism/risk factors  |  |       |                                |                        |   |   |   |
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|  |  |  |   |
|--|--|--|---|
|  |  |  | <u>azelnidipine is</u><br><u>decreased.</u> |
|--|--|--|---|

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