Revision of PRECAUTIONS

Olmesartan medoxomil/azelnidipine

August 27, 2024

Therapeutic category

Antihypertensives

Non-proprietary name

Olmesartan medoxomil/azelnidipine

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

<table>
<tr><th>Current</th><th>Revision</th></tr>
<tr><td>
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)
Patients receiving the following drugs: Azoles (oral dosage form, injections) (itraconazole, miconazole, fluconazole, fosfluconazole, voriconazole), HIV protease inhibitors (preparations containing ritonavir, nelfinavir, atazanavir, fosamprenavir, preparations containing darunavir), preparations containing cobicistat

10. INTERACTIONS
10.1 Contraindications for Co-administration (Do not co-administer with the following.)
<table>
<tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr>
<tr><td>Azoles (oral dosage form, injections)
Itraconazole, miconazole, fluconazole, fosfluconazole, voriconazole</td><td>Co-administration with itraconazole has been reported to result in a 2.8-fold increase in the AUC of azelnidipine.</td><td>It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.</td></tr>
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</td><td>
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)
Patients receiving the following drugs: Itraconazole, miconazole (oral dosage form, injections), fluconazole, fosfluconazole, voriconazole, posaconazole, HIV protease inhibitors (preparations containing ritonavir, nelfinavir, atazanavir, fosamprenavir, preparations containing darunavir), preparations containing cobicistat

10. INTERACTIONS
10.1 Contraindications for Co-administration (Do not co-administer with the following.)
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<tr><td>The following azoles:
Itraconazole, miconazole (oral dosage form or injections), fluconazole, fosfluconazole, voriconazole, posaconazole</td><td>Co-administration of azelnidipine 8 mg with itraconazole 50 mg^{note)} has been reported to result in a 2.8-fold increase in the AUC of azelnidipine.</td><td>It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.</td></tr>
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Note) This is based on the results of a co-administration study with low-dose itraconazole. Refer to the electronic package insert of itraconazole for the dose of itraconazole.
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<tr>
<td>10.2 Precautions for Co-Administration (This drug should be administered with caution when co-administered with the following.)
(N/A)</td>
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<tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr>
<tr><td>Azoles (excluding drugs which are contraindicated for co-administration) Fosravuconazole, etc.</td><td>The effect of azelnidipine may be enhanced. If necessary, the prescription should be switched to the one in which azelnidipine, which is the ingredient of this drug, is reduced in dosage or discontinued, or the administration of these drugs should be discontinued.</td><td>It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.</td></tr>
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