

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

Azelinidipine

August 27, 2024

Therapeutic category

Antihypertensives

Non-proprietary name

Azelinidipine

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision												
<p>2. CONTRAINDICATIONS(This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: <u>Azoles (oral dosage form, injections)</u> (itraconazole, miconazole, fluconazole, fosfluconazole, voriconazole), HIV protease inhibitors (preparations containing ritonavir, nelfinavir, atazanavir, fosamprenavir, preparations containing darunavir), preparations containing cobicistat</p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: Itraconazole, miconazole (<u>oral dosage form, injections</u>), fluconazole, fosfluconazole, voriconazole, <u>posaconazole</u>, HIV protease inhibitors (preparations containing ritonavir, nelfinavir, atazanavir, fosamprenavir, preparations containing darunavir), preparations containing cobicistat</p>												
<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>	<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>												
<table><tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr><tr><td>Azoles (<u>oral dosage form, injections</u>) 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></table>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Azoles (<u>oral dosage form, injections</u>) Itraconazole, miconazole, fluconazole, fosfluconazole, voriconazole	Co-administration with itraconazole has been reported to result in a 2.8-fold increase in the AUC of azelnidipine.	It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.	<table><tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr><tr><td><u>The following azoles</u> Itraconazole, miconazole (<u>oral dosage form, injections</u>), fluconazole, fosfluconazole, voriconazole, <u>posaconazole</u></td><td>Co-administration of <u>azelnidipine 8 mg</u> with itraconazole <u>50 mg^{note)}</u> 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></table> <p><u>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.</u></p>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>The following azoles</u> Itraconazole, miconazole (<u>oral dosage form, injections</u>), fluconazole, fosfluconazole, voriconazole, <u>posaconazole</u>	Co-administration of <u>azelnidipine 8 mg</u> with itraconazole <u>50 mg^{note)}</u> has been reported to result in a 2.8-fold increase in the AUC of azelnidipine.	It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.
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<p>10.2 Precautions for Co-Administration (This drug should be administered with caution when co-administered with the following.)</p>	<p>10.2 Precautions for Co-Administration (This drug should be administered with caution when co-administered with the following.)</p>												

(N/A)	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
	<u>Azoles (excluding drugs which are contraindicated for co-administration) Fosravuconazole, etc.</u>	<u>The effect of azelnidipine may be enhanced. If necessary, azelnidipine should be reduced in dosage or discontinued, or the administration of these drugs should be discontinued.</u>	<u>It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.</u>

Note: 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.