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

August 27, 2024

Therapeutic category

Antihypertensives

Non-proprietary name

Olmesartan medoxomil/azelnidipine

Safety measure

PRECAUTIONS should be revised.

Current

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

Patients receiving the following drugs: <u>Azoles (oral dosage form, injections) (itraconazole, miconazole, fluconazole, fosfluconazole, voriconazole)</u>, 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.)

Drugs	Signs, symptoms,	Mechanism/risk
	and treatment	factors
Azoles (oral dosage	Co-administration	It is considered that
form, injections)	with itraconazole	these drugs inhibit
Itraconazole,	has been reported to	CYP3A4 and that
miconazole,	result in a 2.8-fold	the clearance of
fluconazole,	increase in the AUC	azelnidipine is
fosfluconazole,	of azelnidipine.	decreased.
voriconazole		

Revision

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.)

Drugs	Signs, symptoms,	Mechanism /risk
	and treatment	factors
azoles: Itraconazole, miconazole (oral dosage form or injections), fluconazole,	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.	It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.

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.

10.2 Precautions for Co-Administration (This drug should be administered with caution when co-administered with the following.)
(N/A)

10.2 Precautions for Co-Administration (This drug should be administered with caution when co-administered with the following.)

administration with addition and administration with the following.			
Drugs	Signs, symptoms,	Mechanism/risk	
	and treatment	factors	
Azoles (excluding drugs which are contraindicated for co-administration) Fosravuconazole, etc.	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.	It is considered that these drugs inhibit CYP3A4 and that the clearance of azelnidipine is decreased.	