

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

Darunavir ethanolate/cobicistat

March 17, 2026

Therapeutic category

Anti-virus agents

Non-proprietary name

Darunavir ethanolate/cobicistat

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 rifampicin, phenobarbital, phenytoin, fosphenytoin, carbamazepine, food containing St. John's Wort, triazolam, midazolam, pimozone, simvastatin, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, ergometrine, methylethergometrine, vardenafil, sildenafil (Revatio), tadalafil (Adcirca), blonanserin, azelnidipine, azelnidipine/olmesartan medoxomil, lurasidone, lomitapide, finerenone, voclosporin, ivabradine, venetoclax (relapsed or refractory chronic lymphocytic leukaemia [including small lymphocytic lymphoma] during the dose escalation phase), isavuconazonium sulfate, anamorelin hydrochloride, mavacamten, rivaroxaban, or ticagrelor</p>			<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving rifampicin, phenobarbital, phenytoin, fosphenytoin, carbamazepine, <u>apalutamide, enzalutamide</u>, food containing St. John's Wort, triazolam, midazolam, pimozone, simvastatin, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, ergometrine, methylethergometrine, vardenafil, sildenafil (Revatio), tadalafil (Adcirca), blonanserin, azelnidipine, <u>azelnidipine/olmesartan medoxomil, eplerenone</u>, lurasidone, lomitapide, finerenone, voclosporin, ivabradine, venetoclax (relapsed or refractory chronic lymphocytic leukaemia [including small lymphocytic lymphoma] during the dose escalation phase), isavuconazonium sulfate, anamorelin hydrochloride, mavacamten, rivaroxaban, or ticagrelor</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>		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Rifampicin	The blood concentration of	The CYP3A-inducing activity	Rifampicin	The blood concentration of	The CYP3A-inducing activity
Phenobarbital			Phenobarbital		

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Phenytoin Fosphenytoin Carbamazepine	darunavir and cobicistat may decrease, leading to attenuation of the effects of darunavir ethanolate/cobicistat.	of these drugs promotes the metabolism of darunavir and cobicistat.	Phenytoin Fosphenytoin Carbamazepine <u>Apalutamide</u> <u>Enzalutamide</u>	darunavir and cobicistat may decrease, leading to attenuation of the effects of darunavir ethanolate/cobicistat.	of these drugs promotes the metabolism of darunavir and cobicistat.
(N/A)			Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
			<u>Eplerenone</u>	<u>The blood concentration of eplerenone may increase, and an increase in serum potassium levels may be induced.</u>	<u>The CYP3A inhibitory activity of darunavir and cobicistat suppresses the metabolism of eplerenone.</u>

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