

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/emtricitabine/tenofovir alafenamide fumarate

March 17, 2026

Therapeutic category

Anti-virus agents

Non-proprietary name

Darunavir ethanolate/cobicistat/emtricitabine/tenofovir alafenamide fumarate

Safety measure

PRECAUTIONS should be revised.

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.

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, methylergometrine, 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</u>, food containing St. John's Wort, <u>enzalutamide</u>, triazolam, midazolam, pimozone, simvastatin, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, ergometrine, methylergometrine, vardenafil, sildenafil (Revatio), tadalafil (Adcirca), blonanserin, azelnidipine, azelnidipine/olmesartan medoxomil, <u>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	It is considered	Rifampicin	The blood	It is considered

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.

Phenobarbital Phenytoin Fosphenytoin Carbamazepine	concentration of darunavir, cobicistat, and tenofovir alafenamide may decrease, leading to attenuation of the effects of this drug.	that these drugs induce CYP3A and P-glycoprotein.	Phenobarbital Phenytoin Fosphenytoin Carbamazepine <u>Apalutamide</u>	concentration of darunavir, cobicistat, and tenofovir alafenamide may decrease, leading to attenuation of the effects of this drug.	that these drugs induce CYP3A and P-glycoprotein.
(N/A)			Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
			<u>Enzalutamide</u>	<u>The blood concentration of darunavir and cobicistat may decrease, leading to attenuation of the effects of this drug.</u>	<u>It is considered that enzalutamide induces CYP3A.</u>
			<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>

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.

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