

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

Rilpivirine hydrochloride/emtricitabine/tenofovir alafenamide fumarate

March 17, 2026

Therapeutic category

Anti-virus agents

Non-proprietary name

Rilpivirine hydrochloride/emtricitabine/tenofovir alafenamide fumarate

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, rifabutin, carbamazepine, phenobarbital, phenytoin, phenytoin/phenobarbital, fosphenytoin, <u>dexamethasone (systemic administration) (excluding single administration), food containing St. John's Wort</u>, or proton pump inhibitors (omeprazole, lansoprazole, aspirin/lansoprazole, rabeprazole, esomeprazole, vonoprazan fumarate, aspirin/vonoprazan fumarate)</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <p>(N/A)</p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving rifampicin, rifabutin, carbamazepine, phenobarbital, phenytoin, phenytoin/phenobarbital, fosphenytoin, <u>apalutamide, food containing St. John's Wort, enzalutamide, dexamethasone (systemic administration) (excluding single administration)</u>, or proton pump inhibitors (omeprazole, lansoprazole, aspirin/lansoprazole, rabeprazole, esomeprazole, vonoprazan fumarate, aspirin/vonoprazan fumarate)</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <table border="1" data-bbox="1131 970 1982 1398"> <thead> <tr> <th data-bbox="1131 970 1473 1066">Drugs</th> <th data-bbox="1473 970 1758 1066">Signs, symptoms, and treatment</th> <th data-bbox="1758 970 1982 1066">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1131 1066 1473 1398"><u>Apalutamide</u></td> <td data-bbox="1473 1066 1758 1398"><u>The blood concentration of rilpivirine and tenofovir alafenamide may decrease, leading to attenuation of the effects of this</u></td> <td data-bbox="1758 1066 1982 1398"><u>The CYP3A-inducing activity of apalutamide promotes the metabolism of rilpivirine. The P-glycoprotein-</u></td> </tr> </tbody> </table>		Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Apalutamide</u>	<u>The blood concentration of rilpivirine and tenofovir alafenamide may decrease, leading to attenuation of the effects of this</u>	<u>The CYP3A-inducing activity of apalutamide promotes the metabolism of rilpivirine. The P-glycoprotein-</u>
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		<u>drug.</u>	<u>inducing activity</u> <u>of apalutamide</u> <u>may decrease</u> <u>the plasma</u> <u>concentration of</u> <u>tenofovir</u> <u>alafenamide.</u>
	<u>Enzalutamide</u>	<u>The blood</u> <u>concentration of</u> <u>rilpivirine may</u> <u>decrease, leading to</u> <u>attenuation of the</u> <u>effects of this drug.</u>	<u>The CYP3A-</u> <u>inducing activity</u> <u>of enzalutamide</u> <u>promotes the</u> <u>metabolism of</u> <u>rilpivirine.</u>

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