

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

Apalutamide

March 17, 2026

Therapeutic category

Other antitumor agents

Non-proprietary name

Apalutamide

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current			Revision		
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients receiving nirmatrelvir/ritonavir, ensitrelvir fumaric acid, <u>or</u> lenacapavir sodium			2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients receiving nirmatrelvir/ritonavir, ensitrelvir fumaric acid, lenacapavir sodium, <u>elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate, darunavir ethanolate/cobicistat/emtricitabine/tenofovir alafenamide fumarate, bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate, rilpivirine hydrochloride/emtricitabine/tenofovir alafenamide fumarate, darunavir ethanolate/cobicistat, doravirine, dolutegravir sodium/rilpivirine hydrochloride, rilpivirine, or rilpivirine hydrochloride</u>		
10. INTERACTIONS 10.1 Contraindications for Co-administration (Do not co-administer with the following.)			10. INTERACTIONS 10.1 Contraindications for Co-administration (Do not co-administer with the following.)		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Lenacapavir sodium	Since the blood concentration of <u>lenacapavir</u> decreases, <u>its</u> effects may decrease, and resistance to	Apalutamide induces CYP3A and P-gp.	Lenacapavir sodium <u>Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate</u> <u>Darunavir</u>	Since the blood concentration of <u>these drugs</u> decreases, <u>their</u> effects may	Apalutamide induces CYP3A and P-gp.

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	<u>lenacapavir</u> may develop.		<u>ethanolate/cobicistat/emtricitabine/tenofovir alafenamide fumarate</u> <u>Bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate</u> <u>Rilpivirine hydrochloride/emtricitabine/tenofovir alafenamide fumarate</u>	decrease, and resistance to <u>these drugs</u> may develop.								
(N/A)				<table border="1"> <thead> <tr> <th data-bbox="1126 778 1473 874">Drugs</th> <th data-bbox="1473 778 1760 874">Signs, symptoms, and treatment</th> <th data-bbox="1760 778 1984 874">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1126 874 1473 1265"> <u>Darunavir ethanolate/cobicistat</u> <u>Doravirine</u> <u>Dolutegravir sodium/rilpivirine hydrochloride</u> <u>Rilpivirine</u> <u>Rilpivirine hydrochloride</u> </td> <td data-bbox="1473 874 1760 1265"> <u>Since the blood concentration of these drugs decreases, their effects may decrease, and resistance to these drugs may develop.</u> </td> <td data-bbox="1760 874 1984 1265"> <u>Apalutamide induces CYP3A.</u> </td> </tr> </tbody> </table>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Darunavir ethanolate/cobicistat</u> <u>Doravirine</u> <u>Dolutegravir sodium/rilpivirine hydrochloride</u> <u>Rilpivirine</u> <u>Rilpivirine hydrochloride</u>	<u>Since the blood concentration of these drugs decreases, their effects may decrease, and resistance to these drugs may develop.</u>	<u>Apalutamide induces CYP3A.</u>		
	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors									
<u>Darunavir ethanolate/cobicistat</u> <u>Doravirine</u> <u>Dolutegravir sodium/rilpivirine hydrochloride</u> <u>Rilpivirine</u> <u>Rilpivirine hydrochloride</u>	<u>Since the blood concentration of these drugs decreases, their effects may decrease, and resistance to these drugs may develop.</u>	<u>Apalutamide induces CYP3A.</u>										

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