

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

Dolutegravir sodium/rilpivirine hydrochloride

March 17, 2026

Therapeutic category

Anti-virus agents

Non-proprietary name

Dolutegravir sodium/rilpivirine hydrochloride

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, carbamazepine, phenytoin, fosphenytoin sodium hydrate, phenobarbital, food containing St. John's Wort, dexamethasone (systemic administration) (excluding single administration), or proton pump inhibitors (omeprazole, lansoprazole, rabeprazole sodium, esomeprazole magnesium hydrate, 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, carbamazepine, phenytoin, fosphenytoin sodium hydrate, phenobarbital, food containing St. John's Wort, <u>apalutamide, enzalutamide</u>, dexamethasone (systemic administration) (excluding single administration), or proton pump inhibitors (omeprazole, lansoprazole, rabeprazole sodium, esomeprazole magnesium hydrate, 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="1133 874 1995 1361"> <thead> <tr> <th data-bbox="1133 874 1473 970">Drugs</th> <th data-bbox="1478 874 1760 970">Signs, symptoms, and treatment</th> <th data-bbox="1765 874 1995 970">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1133 973 1473 1361"> <p><u>Apalutamide</u></p> <p><u>Enzalutamide</u></p> </td> <td data-bbox="1478 973 1760 1361"> <p><u>The blood concentration of rilpivirine may decrease, leading to attenuation of the effects of dolutegravir sodium/rilpivirine hydrochloride.</u></p> </td> <td data-bbox="1765 973 1995 1361"> <p><u>The CYP3A-inducing activity of these drugs promotes the metabolism of rilpivirine.</u></p> </td> </tr> </tbody> </table>		Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<p><u>Apalutamide</u></p> <p><u>Enzalutamide</u></p>	<p><u>The blood concentration of rilpivirine may decrease, leading to attenuation of the effects of dolutegravir sodium/rilpivirine hydrochloride.</u></p>	<p><u>The CYP3A-inducing activity of these drugs promotes the metabolism of rilpivirine.</u></p>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.