

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

Vardenafil hydrochloride hydrate

March 17, 2026

Therapeutic category

Other agents for uro-genital and anal organ

Non-proprietary name

Vardenafil hydrochloride hydrate

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 the following drugs: Riociguat, CYP3A4 inhibitors (ritonavir, atazanavir, fosamprenavir, lopinavir/ritonavir, nirmatrelvir/ritonavir, preparations containing darunavir, ketoconazole (excluding topical formulations), itraconazole, ensitrelvir, preparations containing cobicistat)</p> <p>10. INTERACTIONS</p> <p>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 the following drugs: Riociguat, CYP3A4 inhibitors (ritonavir, atazanavir, fosamprenavir, lopinavir/ritonavir, nirmatrelvir/ritonavir, preparations containing darunavir, ketoconazole (excluding topical formulations), itraconazole, ensitrelvir, preparations containing cobicistat, <u>ceritinib</u>)</p> <p>10. INTERACTIONS</p> <p>Contraindications for Co-administration (Do not co-administer with the following.)</p> <table border="1" data-bbox="1133 874 2000 1209"> <thead> <tr> <th data-bbox="1133 874 1487 948">Drugs</th> <th data-bbox="1491 874 1751 948">Signs, symptoms, and treatment</th> <th data-bbox="1756 874 2000 948">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1133 951 1487 1209"><u>Ceritinib</u></td> <td data-bbox="1491 951 1751 1209"><u>The plasma concentration of vardenafil hydrochloride hydrate may increase.</u></td> <td data-bbox="1756 951 2000 1209"><u>The clearance of vardenafil hydrochloride hydrate is decreased by the inhibition of CYP3A4.</u></td> </tr> </tbody> </table>			Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Ceritinib</u>	<u>The plasma concentration of vardenafil hydrochloride hydrate may increase.</u>	<u>The clearance of vardenafil hydrochloride hydrate is decreased by the inhibition of CYP3A4.</u>
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