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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. The PMDA shall not be responsible for any consequences resulting from the use of this English version.

Revision of PRECAUTIONS

Rivaroxaban

May 8, 2024

Therapeutic category

Anticoagulants

Non-proprietary name

Rivaroxaban

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><Common to all indications></p> <p>Patients receiving oral dosage form or injections of azoles (itraconazole, voriconazole, miconazole, ketoconazole)</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>			<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p><Common to all indications></p> <p>Patients receiving oral dosage form or injections of azoles (itraconazole, voriconazole, miconazole, <u>posaconazole</u>, ketoconazole)</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
<p>The following azoles (oral dosage form or injections)</p> <p>Itraconazole</p> <p>Voriconazole</p> <p>Miconazole</p> <p>Ketoconazole (not marketed in Japan)</p>	<p>The blood concentration of this drug may increase, resulting in the enhancement of the anticoagulant effect and concerns about an increased risk of haemorrhage.</p>	<p>The clearance of this drug is decreased by the potent inhibition of CYP3A4 and inhibition of P-glycoprotein.</p>	<p>The following azoles (oral dosage form or injections)</p> <p>Itraconazole</p> <p>Voriconazole</p> <p>Miconazole</p> <p><u>Posaconazole</u></p> <p>Ketoconazole (not marketed in Japan)</p>	<p>The blood concentration of this drug may increase, resulting in the enhancement of the anticoagulant effect and concerns about an increased risk of haemorrhage.</p>	<p>The clearance of this drug is decreased by the potent inhibition of CYP3A4 and inhibition of P-glycoprotein.</p>

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