

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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

Posaconazole

May 8, 2024

Therapeutic category

Antibiotic preparations acting mainly on mold

Non-proprietary name

Posaconazole

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revised language is underlined.

Current	Revision						
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: Ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, methylergometrine, ergometrine, simvastatin, atorvastatin, pimozide, quinidine, venetoclax [during its dose escalation phase for relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma)], suvorexant, lurasidone hydrochloride, blonanserin, triazolam</p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving the following drugs: Ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, methylergometrine, ergometrine, simvastatin, atorvastatin, pimozide, quinidine, venetoclax [during its dose escalation phase for relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma)], suvorexant, lurasidone hydrochloride, blonanserin, triazolam, <u>rivaroxaban</u></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>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p> <table><tr><th>Drugs</th><th>Signs, symptoms, and treatment</th><th>Mechanism/risk factors</th></tr><tr><td><u>Rivaroxaban</u></td><td><u>The anticoagulant effect of rivaroxaban may be enhanced, and a risk of haemorrhage may be increased.</u></td><td><u>The plasma concentration of rivaroxaban is expected to rise due to the inhibition of CYP3A4, as well as the possible inhibition of P-gp, by co-administration with posaconazole.</u></td></tr></table>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Rivaroxaban</u>	<u>The anticoagulant effect of rivaroxaban may be enhanced, and a risk of haemorrhage may be increased.</u>	<u>The plasma concentration of rivaroxaban is expected to rise due to the inhibition of CYP3A4, as well as the possible inhibition of P-gp, by co-administration with posaconazole.</u>
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors					
<u>Rivaroxaban</u>	<u>The anticoagulant effect of rivaroxaban may be enhanced, and a risk of haemorrhage may be increased.</u>	<u>The plasma concentration of rivaroxaban is expected to rise due to the inhibition of CYP3A4, as well as the possible inhibition of P-gp, by co-administration with posaconazole.</u>					

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp