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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.*

# Revision of Precautions

## Posaconazole

December 8, 2020

### **Therapeutic category**

Antibiotic preparations acting mainly on mold

### **Non-proprietary name**

Posaconazole

### **Safety measure**

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision														
<p>2. CONTRAINDICATIONS</p> <p>Patients receiving ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, methylergometrine, ergometrine, simvastatin, atorvastatin, pimozide, or quinidine</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p> <p>(N/A)</p> <p>10.2 Precautions for Co-administration</p> <p>(N/A)</p>	<p>2. CONTRAINDICATIONS</p> <p>Patients receiving ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine, methylergometrine, ergometrine, simvastatin, atorvastatin, pimozide, quinidine, <u>or venetoclax (during its dose escalation phase)</u></p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p> <table border="1" data-bbox="1131 730 1982 1090"> <thead> <tr> <th data-bbox="1131 730 1415 810">Drugs</th> <th data-bbox="1417 730 1697 810">Signs, symptoms, and treatment</th> <th data-bbox="1700 730 1982 810">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1131 812 1415 1090"><u>Venetoclax (during its dose escalation phase)</u></td> <td data-bbox="1417 812 1697 1090"><u>Co-administration of this drug with venetoclax during its dose escalation phase may increase the risk of tumor lysis syndrome.</u></td> <td data-bbox="1700 812 1982 1090"><u>Plasma concentration of venetoclax is expected to rise due to inhibition of CYP3A by co-administration of posaconazole.</u></td> </tr> </tbody> </table> <p>10.2 Precautions for Co-administration</p> <table border="1" data-bbox="1131 1185 1982 1303"> <thead> <tr> <th data-bbox="1131 1185 1415 1265">Drugs</th> <th data-bbox="1417 1185 1697 1265">Signs, symptoms, and treatment</th> <th data-bbox="1700 1185 1982 1265">Mechanism/risk factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1131 1267 1415 1303"><u>Venetoclax (during</u></td> <td data-bbox="1417 1267 1697 1303"><u>When co-</u></td> <td data-bbox="1700 1267 1982 1303"><u>Plasma</u></td> </tr> </tbody> </table>			Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Venetoclax (during its dose escalation phase)</u>	<u>Co-administration of this drug with venetoclax during its dose escalation phase may increase the risk of tumor lysis syndrome.</u>	<u>Plasma concentration of venetoclax is expected to rise due to inhibition of CYP3A by co-administration of posaconazole.</u>	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	<u>Venetoclax (during</u>	<u>When co-</u>	<u>Plasma</u>
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	<u>its maintenance phase)</u>	<u>administered with venetoclax during its maintenance phase, doses of venetoclax should be reduced and patients should be closely monitored for any signs of adverse reactions related to venetoclax.</u>	<u>concentration of venetoclax is expected to rise due to inhibition of CYP3A by co-administration with posaconazole.</u>
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