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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.

Revision of Precautions

Atazanavir sulfate

September 13, 2022

Therapeutic category

Anti-virus agents

Non-proprietary name

Atazanavir sulfate

Safety measure

Precautions should be revised.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current			Revision						
<p>2. CONTRAINDICATIONS</p> <p>Patients receiving the following drugs: Rifampicin, irinotecan hydrochloride hydrate, midazolam, triazolam, bepridil hydrochloride hydrate, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine mesilate, ergometrine maleate, methylergometrine maleate, pimozide, simvastatin, lovastatin (not marketed in Japan), lomitapide mesilate, vardenafil hydrochloride hydrate, blonanserin, azelnidipine, olmesartan medoxomil/azelnidipine, lurasidone hydrochloride, rivaroxaban, <u>riociguat</u>, grazoprevir hydrate, glecaprevir hydrate/pibrentasvir, proton pump inhibitors (omeprazole, lansoprazole, rabeprazole, esomeprazole, vonoprazan fumarate), aspirin/lansoprazole, aspirin/vonoprazan fumarate, or St. John's Wort</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p> <table border="1"> <thead> <tr> <th>Drugs</th> <th>Signs, Symptoms, and Treatment</th> <th>Mechanism and Risk Factors</th> </tr> </thead> <tbody> <tr> <td><u>Riociguat</u></td> <td><u>It has been reported that the blood concentration of riociguat was increased</u></td> <td><u>The clearance of riociguat is decreased by the inhibition of multiple CYP isoforms</u></td> </tr> </tbody> </table>			Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	<u>Riociguat</u>	<u>It has been reported that the blood concentration of riociguat was increased</u>	<u>The clearance of riociguat is decreased by the inhibition of multiple CYP isoforms</u>	<p>2. CONTRAINDICATIONS</p> <p>Patients receiving the following drugs: Rifampicin, irinotecan hydrochloride hydrate, midazolam, triazolam, bepridil hydrochloride hydrate, ergotamine tartrate/anhydrous caffeine/isopropylantipyrine, dihydroergotamine mesilate, ergometrine maleate, methylergometrine maleate, pimozide, simvastatin, lovastatin (not marketed in Japan), lomitapide mesilate, vardenafil hydrochloride hydrate, blonanserin, azelnidipine, olmesartan medoxomil/azelnidipine, lurasidone hydrochloride, rivaroxaban, grazoprevir hydrate, glecaprevir hydrate/pibrentasvir, proton pump inhibitors (omeprazole, lansoprazole, rabeprazole, esomeprazole, vonoprazan fumarate), aspirin/lansoprazole, aspirin/vonoprazan fumarate, or St. John's Wort</p> <p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p> <p>(deleted)</p>
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	<u>and the clearance of riociguat was decreased when co-administered with ketoconazole.</u>	<u>(CYP1A1, CYP3A, etc.) and P-gp/breast cancer resistance protein (BCRP).</u>							
<p>10.2 Precautions for Co-administration (N/A)</p>			<p>10.2 Precautions for Co-administration</p> <table border="1"> <thead> <tr> <th data-bbox="1126 443 1384 539">Drugs</th> <th data-bbox="1384 443 1704 539">Signs, Symptoms, and Treatment</th> <th data-bbox="1704 443 2000 539">Mechanism and Risk Factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1126 539 1384 1118"> <u>Riociguat</u> </td> <td data-bbox="1384 539 1704 1118"> <u>The blood concentration of riociguat may increase. When co- administration with atazanavir sulfate is necessary, patients should be monitored for their conditions and dose reduction of riociguat should be considered as necessary.</u> </td> <td data-bbox="1704 539 2000 1118"> <u>The clearance of riociguat is decreased by the inhibition of CYP3A4 by atazanavir sulfate.</u> </td> </tr> </tbody> </table>	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	<u>Riociguat</u>	<u>The blood concentration of riociguat may increase. When co- administration with atazanavir sulfate is necessary, patients should be monitored for their conditions and dose reduction of riociguat should be considered as necessary.</u>	<u>The clearance of riociguat is decreased by the inhibition of CYP3A4 by atazanavir sulfate.</u>
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N/A: Not Applicable. No corresponding language is included in the current Precautions.

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