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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

## Blonanserin (patches)

December 17, 2021

### **Therapeutic category**

Psychotropic agents

### **Non-proprietary name**

Blonanserin

### **Safety measure**

Precautions should be revised in the package insert.

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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 azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injections), fluconazole, fosfluconazole), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), or preparations containing cobicistat</p>			<p>2. CONTRAINDICATIONS</p> <p>Patients receiving azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injections), fluconazole, fosfluconazole, <u>posaconazole</u>), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), or preparations containing cobicistat</p>		
<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p>			<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration</p>		
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
<p>Drugs that strongly inhibit CYP3A4</p> <p>[Azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injections), fluconazole, fosfluconazole),</p>	<p>The blood concentration of this drug may increase, and the effects may be enhanced.</p>	<p>Clearance may decrease since these drugs inhibit CYP3A4, the major metabolic enzymes of this drug.</p>	<p>Drugs that strongly inhibit CYP3A4</p> <p>[Azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injections), fluconazole, fosfluconazole, <u>posaconazole</u>,</p>	<p>The blood concentration of this drug may increase, and the effects may be enhanced.</p>	<p>Clearance may decrease since these drugs inhibit CYP3A4, the major metabolic enzymes of this drug.</p>

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HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), preparations containing cobicistat]			<u>posaconazole</u> ), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), preparations containing cobicistat]		
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