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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

Blonanserin (oral dosage form)

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 Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

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

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<p>HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), preparations containing cobicistat]</p>		<p>reported overseas that the AUC and C_{max} of this drug increased 17-fold and 13-fold, respectively, when co-administered with ketoconazole (oral dosage form; not marketed in Japan).</p>	<p><u>posaconazole</u>), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), preparations containing cobicistat]</p>		<p>reported overseas that the AUC and C_{max} of this drug increased 17-fold and 13-fold, respectively, when co-administered with ketoconazole (oral dosage form; not marketed in Japan).</p>
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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, injectable dosage forms), 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, injectable dosage forms), 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>		
	Signs, Symptoms, and Treatment	Mechanism and Risk Factors		Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Drugs that strongly inhibit CYP3A4 [Azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injectable dosage forms),	The blood concentration of this drug may increase, and the effects may be enhanced.	Oral clearance may decrease since these drugs inhibit CYP3A4, the major metabolic enzymes of this	Drugs that strongly inhibit CYP3A4 [Azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injectable dosage forms),	The blood concentration of this drug may increase, and the effects may be enhanced.	Oral clearance may decrease since these drugs inhibit CYP3A4, the major metabolic enzymes of this

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<p>fluconazole, fosfluconazole), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), preparations containing cobicistat]</p>		<p>drug. It has been reported overseas that the AUC and C_{max} of this drug increased 17-fold and 13-fold, respectively, when co-administered with ketoconazole (oral dosage form; not marketed in Japan).</p>	<p>fluconazole, fosfluconazole, <u>posaconazole</u>), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), preparations containing cobicistat]</p>		<p>drug. It has been reported overseas that the AUC and C_{max} of this drug increased 17-fold and 13-fold, respectively, when co-administered with ketoconazole (oral dosage form; not marketed in Japan).</p>
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