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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 (oral dosage form)

December 17, 2021

Therapeutic category

Psychotropic agents

Non-proprietary name

Blonanserin

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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.

Pharmaceutical Affairs Bureau, MHVV, dated April 25, 1997 (Old Instruction	ons): Revised language is underlined	
Current	Revision	
Contraindications	Contraindications	
Patients receiving azole antifungal agents (itraconazole,	Patients receiving azole antifungal agents (itraconazole,	
voriconazole, miconazole (oral dosage form, oral preparation,	voriconazole, miconazole (oral dosage form, oral preparation,	
injectable dosage forms), fluconazole, fosfluconazole), HIV protease	injectable dosage forms), fluconazole, fosfluconazole,	
inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir,	posaconazole), HIV protease inhibitors (ritonavir, lopinavir/ritonavir	
darunavir, atazanavir, fosamprenavir), or preparations containing	combination agents, nelfinavir, darunavir, atazanavir,	
cobicistat	fosamprenavir), or preparations containing cobicistat	
Drug Interactions	Drug Interactions	
Contraindications for Co-administration	Contraindications for Co-administration	
Signs,	Signs,	

Drugs	Signs, Symptoms,	Mechanism and Risk Factors
	and Treatment	
Drugs that strongly inhibit	The blood	Oral clearance
CYP3A4	concentration	may decrease
[Azole antifungal agents	of this drug	since these
(itraconazole, voriconazole,	may increase,	drugs inhibit
miconazole (oral dosage	and the effects	CYP3A4, the
form, oral preparation,	may be	major metabolic
injectable dosage form),	enhanced.	enzymes of this
fluconazole, fosfluconazole),		drug. It has been

Mechanism and Drugs Symptoms, and Risk Factors Treatment Drugs that strongly inhibit The blood Oral clearance CYP3A4 may decrease concentration [Azole antifungal agents of this drug since these (itraconazole, voriconazole, drugs inhibit may increase, miconazole (oral dosage and the effects CYP3A4, the form, oral preparation, may be major metabolic injectable dosage form), enhanced. enzymes of this fluconazole, fosfluconazole, drug. It has been

HIV protocce inhibitors	reported	noccoonszolo) HIV	roported
HIV protease inhibitors	reported	posaconazole), HIV	reported
(ritonavir, lopinavir/ritonavir	overseas that the	protease inhibitors	overseas that the
combination agents,	AUC and C _{max} of	(ritonavir, lopinavir/ritonavir	AUC and C _{max} of
nelfinavir, darunavir,	this drug	combination agents,	this drug
atazanavir, fosamprenavir),	increased 17-fold	nelfinavir, darunavir,	increased 17-fold
preparations containing	and 13-fold,	atazanavir, fosamprenavir),	and 13-fold,
cobicistat]	respectively,	preparations containing	respectively,
	when co-	cobicistat]	when co-
	administered		administered
	with		with
	ketoconazole		ketoconazole
	(oral dosage		(oral dosage
	form; not		form; not
	marketed in		marketed in
	Japan).		Japan).

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.

2. CONTRAINDICATIONS

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

Current

10. INTERACTIONS

10.1 Contraindications for Co-administration

	Signs,	
Drugo	Symptoms,	Mechanism and
Drugs	and	Risk Factors
	Treatment	
Drugs that strongly inhibit	The blood	Oral clearance
CYP3A4	concentration	may decrease
[Azole antifungal agents	of this drug	since these
(itraconazole, voriconazole,	may increase,	drugs inhibit
miconazole (oral dosage	and the	CYP3A4, the
form, oral preparation,	effects may	major metabolic
injectable dosage forms),	be enhanced.	enzymes of this

2. CONTRAINDICATIONS

Patients receiving azole antifungal agents (itraconazole, voriconazole, miconazole (oral dosage form, oral preparation, injectable dosage forms), fluconazole, fosfluconazole, posaconazole), HIV protease inhibitors (ritonavir, lopinavir/ritonavir combination agents, nelfinavir, darunavir, atazanavir, fosamprenavir), or preparations containing cobicistat

Revision

10. INTERACTIONS

10.1 Contraindications for Co-administration

	Signs,	
Drugs	Symptoms,	Mechanism and
	and	Risk Factors
	Treatment	
Drugs that strongly inhibit	The blood	Oral clearance
CYP3A4	concentration	may decrease
[Azole antifungal agents	of this drug	since these
(itraconazole, voriconazole,	may increase, drugs inhibit	
miconazole (oral dosage	and the CYP3A4, the	
form, oral preparation,	effects may major metabolic	
injectable dosage forms),	be enhanced.	enzymes of this

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