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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

Perospirone hydrochloride hydrate

March 31, 2020

Therapeutic category

Psychotropics

Non-proprietary name

Blonanserin, perospirone hydrochloride hydrate

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.

Current	Revision
Careful Administration	Careful Administration
Patients with Parkinson's disease	Patients with Parkinson's disease or dementia with Lewy bodies

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
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC
BACKGROUNDS	BACKGROUNDS
9.1 Patients with Complication or History of Diseases, etc.	9.1 Patients with Complication or History of Diseases, etc.
Patients with Parkinson's disease	Patients with Parkinson's disease or dementia with Lewy bodies