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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

Memantine hydrochloride

June 16, 2020

Therapeutic category

Central nervous system agents-miscellaneous

Non-proprietary name

Memantine hydrochloride

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Bradyarrhythmia such as complete atrioventricular block and severe sinus bradycardia:</u> <u>Bradyarrhythmia such as complete atrioventricular block and severe sinus bradycardia may occur. Patients should be carefully monitored and if any abnormalities are observed, appropriate measure should be taken such as discontinuing administration of this drug.</u>

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
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Bradyarrhythmia such as complete atrioventricular block and severe sinus bradycardia</u>

N/A: Not Applicable, because the section is not included in the current package insert.

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