Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Methylphenidate hydrochloride (sustained-release tablets)

October 29, 2019

Therapeutic category

Psychotropics

Non-proprietary name

Methylphenidate 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
Warnings This drug should be administered only under physicians, medical institutions, and pharmacies having supervising pharmacists that are versed in the diagnosis and treatment of attention deficit/hyperactivity disorder (AD/HD) and capable of adequately managing the risks and other issues associated with this drug including drug dependence. In addition, such pharmacies should confirm the prescribing physicians and their institutions before dispensing this drug.	Warnings This drug should be administered only to patients who are registered in the management system established as a pre-requisite for marketing authorization, in medical institutions and pharmacies having physicians and pharmacists registered in the management system, respectively. Registered physicians and pharmacists should be versed in the diagnosis and treatment of attention deficit/hyperactivity disorder (AD/HD) and capable of adequately managing the risks and other issues associated with this drug including drug dependence. In addition, such pharmacies should confirm that the prescribing physicians, their institutions, and the patients are registered in the management system before dispensing this drug.
(N/A)	Upon use, patients (patients or their proxy for pediatric use) should be informed, with written materials, of the efficacy and safety of this drug as well as the precautions not to use this drug for any other purposes than prescribed, or not to pass this drug on to anyone else. Their consent also should be confirmed in writing.

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

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