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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Pramipexole hydrochloride hydrate

(sustained-release tablets)

August 22, 2019

Therapeutic category

Antiparkinsonian agents

Non-proprietary name

Pramipexole 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
Important Precautions Rapid dose reduction or discontinuation of this drug may cause syndrome malin. When dose reduction or discontinuation is necessary, the dose should be gradually reduced.	Important Precautions When dose reduction or discontinuation of this drug is necessary, the dose should be gradually reduced. Rapid dose reduction or discontinuation may cause syndrome malin. In addition, rapid dose reduction or discontinuation of dopamine receptor agonists may cause drug withdrawal syndrome (characterized by apathy, anxiety, depression, fatigue, sweating, pain, etc.).
Adverse Reactions Other Adverse Reactions (N/A)	Adverse Reactions Other Adverse Reactions Drug withdrawal syndrome* (apathy, anxiety, depression, fatigue, sweating, pain, etc.) *When any abnormalities are observed, appropriate measures should be taken such as resuming administration or returning the dose to the level prior to reduction.

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

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