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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

Rotigotine

February 25, 2020

Therapeutic category

Antiparkinsonian agents

Central nervous system agents-miscellaneous

Non-proprietary name

Rotigotine

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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>Rhabdomyolysis:</u> <u>Rhabdomyolysis characterized by myalgia, feelings of weakness, increased CK (CPK), increased blood myoglobin, and increased urine myoglobin may occur. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken. Patients should be carefully monitored for signs of acute kidney injury due to rhabdomyolysis.</u>

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

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