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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

Levodopa/carbidopa hydrate/entacapone

January 21, 2020

Therapeutic category

Antiparkinsonian agents

Non-proprietary name

Levodopa/carbidopa hydrate/entacapone

Safety measure

Precautions should be revised in the package insert.

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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
<p>Important Precautions</p> <p>Impulse-control disorder such as pathological gambling (persistent and recurrent gambling behavior despite negative social consequences including ruined personal life), pathologically increased sexual urges, compulsive shopping, and binge eating have been reported in patients receiving levodopa or a dopamine receptor agonist. Reducing the dose or discontinuing the medicine, or other appropriate measures should be taken if such symptoms develop. <u>In addition, patients, their families, or other caregivers should be informed of these symptoms of impulse-control disorder.</u></p>	<p>Important Precautions</p> <p>Impulse-control disorder such as pathological gambling (persistent and recurrent gambling behavior despite negative social consequences including ruined personal life), pathologically increased sexual urges, compulsive shopping, and binge eating have been reported in patients receiving levodopa or a dopamine receptor agonist. <u>In addition to impulse-control disorder, dopamine dysregulation syndrome in which patients seek doses of levodopa in excess of those required also has been reported in patients receiving levodopa. Patients, their families, or other caregivers should be informed of these symptoms</u> and reducing the dose or discontinuing the medicine, or other appropriate measures should be taken if such symptoms develop.</p>

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