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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

Levodopa/carbidopa hydrate Levodopa/benserazide hydrochloride

January 21, 2020

Therapeutic category

Antiparkinsonian agents

Non-proprietary name

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