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.
Important Precautions

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 following administration of levodopa or a dopamine receptor agonist. Reducing the dose or discontinuing the medicine, or other appropriate measures should be taken if such symptoms develop. In addition, patients, their families, or other caregivers should be informed of these symptoms of impulse-control disorder.

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):

<table>
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<th>Current</th>
<th>Revision</th>
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<td>Important Precautions</td>
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<tr>
<td>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 following administration of levodopa or a dopamine receptor agonist. Reducing the dose or discontinuing the medicine, or other appropriate measures should be taken if such symptoms develop. In addition, patients, their families, or other caregivers should be informed of these symptoms of impulse-control disorder.</td>
<td>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 following administration of levodopa or a dopamine receptor agonist. 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 and reducing the dose or discontinuing the medicine, or other appropriate measures should be taken if such symptoms develop.</td>
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