



Summary of investigation results Products Containing Levodopa

April 21, 2016

Non-proprietary name

- a–b. Levodopa
- c–e. Levodopa/Benserazide hydrochloride
- f–g. Levodopa/Carbidopa hydrate
- h. Levodopa/Carbidopa hydrate/Entacapone

Brand name (Marketing authorization holder)

- a. Dopasol Tablets 200 mg (Daiichi Sankyo Co., Ltd.)
- b. Dopaston Capsules 250 mg, Dopaston Powder 98.5%, Dopaston Intravenous Injections 25 mg, 50 mg (Ohara Pharmaceutical Co., Ltd.)
- c. Neodopasol Combination Tablets (Daiichi Sankyo Co., Ltd.)
- d. Madopar Combination Tablets (Chugai Pharmaceutical Co., Ltd.)
- e. EC-Doparl Combination Tablets (Kyowa Hakko Kirin Co., Ltd.)
- f. Neodopaston Combination Tablets L100, L250 (Daiichi Sankyo Co., Ltd.), and the others
- g. Menesit Combination Tablets 100, 250 (MSD K.K.), and the others
- h. Stalevo Combination Tablets L50, L100 (Novartis Pharma K.K.)

Indications

- a. Treatment and prophylaxis of the following symptoms associated with Parkinson's disease/Parkinson's syndrome
 - Akinesia, muscle rigidity, tremor, impaired activities of daily living, mask-like faces, gait disturbance, language disorder, abnormal posture, pulsion, oily face, dysgraphia, psychiatric symptom, and ptyalism
- b–g. Parkinson's disease and Parkinson's syndrome
- h. Parkinson's disease (when circadian rhythm of symptoms [wearing-off] is observed in administration of levodopa/carbidopa)



Summary of revision

“Angle closure glaucoma” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of angle closure glaucoma have been reported in patients treated with products containing levodopa in Japan and overseas. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

- a–b. No case associated with angle closure glaucoma has been reported.
- c–e. A total of 2 cases associated with angle closure glaucoma have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.
- f–g. No case associated with angle closure glaucoma has been reported.
- h. No case associated with angle closure glaucoma has been reported.