



# Summary of Investigation Results

## Preparations containing levodopa

January 21, 2020

### **Non-proprietary name**

- a. Levodopa
- b. Levodopa/carbidopa hydrate
- c. Levodopa/carbidopa hydrate/entacapone
- d. Levodopa/benserazide hydrochloride

### **Branded name (Marketing authorization holder)**

See Attachment

### **Indications**

See Attachment

### **Summary of revisions**

Language concerning dopamine dysregulation syndrome should be added to the Important Precautions section.

### **Investigation results and background of the revision**

Cases of dopamine dysregulation syndrome have been reported in patients treated with levodopa in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors as well as taking into account the language in the European package inserts.



**Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years**

Cases involving dopamine dysregulation syndrome

- a. No cases have been reported to date.
- b. A total of 2 cases have been reported to date (A causal relationship between the drug and event could not be ruled out for either of these cases.)

No patient mortalities have been reported to date.

- c. 1 case has been reported to date (A causal relationship between the drug and event could not be established for this case.)

No patient mortalities have been reported to date.

- d. No cases have been reported to date.



Attachment

	Non-proprietary name	Branded name (Marketing authorization holder)	Indications
a.	Levodopa	Dopaston Capsules 250 mg, Dopaston Powder 98.5%, Dopaston for Intravenous Use 25 mg, 50 mg (Ohara Pharmaceutical Co., Ltd.), Dopasol Tablets 200 mg (Alfresa Pharma Corporation)	Dopaston Capsules 250 mg, Dopaston Powder 98.5%, Dopaston for Intravenous Use 25 mg, 50 mg : Parkinson's disease and Parkinson's syndrome Dopasol Tablets 200 mg : 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 ptialism
b.	Levodopa/ carbidopa hydrate	Neodopaston Combination Tablets L100, L250 (Daiichi Sankyo Co., Ltd.), Menesit Tablets 100, 250 (MSD K.K.), and the others	Parkinson's disease and Parkinson's syndrome
b.	Levodopa/ carbidopa hydrate	Duodopa enteral combination solution (AbbVie GK)	Improvement of circadian change (wearing-off phenomenon) of symptoms of Parkinson's disease in which sufficient effect cannot be



*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

	Non-proprietary name	Branded name (Marketing authorization holder)	Indications
			obtained with existing drug therapy including products containing levodopa
c.	Levodopa/ carbidopa hydrate /entacapone	Stalevo Combination Tablets L50, L100 (Novartis Pharma K.K.)	Parkinson's disease (when circadian rhythm of symptoms [wearing-off] is observed in administration of levodopa/carbidopa)
d.	Levodopa/ benserazide hydrochloride	Neodopasol Combination Tablets (Alfresa Pharma Corporation), EC-DoparI Tablets (Kyowa Kirin Co., Ltd.), Madopar Combination Tablet (Taiyo Pharma Co., Ltd.)	Parkinson's disease and Parkinson's syndrome