

Launch of Ongentys® Tablets 25mg, a Peripheral COMT Inhibitor in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President and Representative Director: Gyo Sagara; "ONO") announced today that it has launched Ongentys® (generic name: opicapone) Tablets 25mg ("Ongentys"), a catechol-O-methyltransferase (COMT) inhibitor, in Japan for the improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) in Parkinson's disease in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride.

Parkinson's disease is a progressive neurodegenerative disease presenting motor symptoms such as bradykinesia, tremor and muscle rigidity. The number of patients with Parkinson's disease in Japan is estimated to be approximately 163,000*. The symptoms of Parkinson's disease are caused by degenerative loss of dopamine containing neurons in the substantia nigra and the impaired dopaminergic function of the basal ganglia.

Levodopa, usually administered in combination with a DDCi, which inhibits the activity of the main pathway of levodopa metabolism (decarboxylation) and improves levodopa's distribution in the central nervous system and short-duration response to levodopa, is the most effective symptomatic treatment for Parkinson's disease. However, levodopa/DDCi preparations are required to be taken several times per day due to levodopa's short half-life. When the patient develops wearing-off phenomenon due to Parkinson's disease progression and levodopa's short duration of action, adjunctive therapy to levodopa/DDCi is often necessary. A COMT inhibitor (COMTi), one of the adjunctive therapies to levodopa/DDCi, acts by inhibiting the COMT enzyme, which is responsible for alternative pathway of levodopa metabolism, and prolongs levodopa's duration of action, like DDCi. Therefore, they are useful in reducing OFF-time in patients with Parkinson's disease and wearing-off.

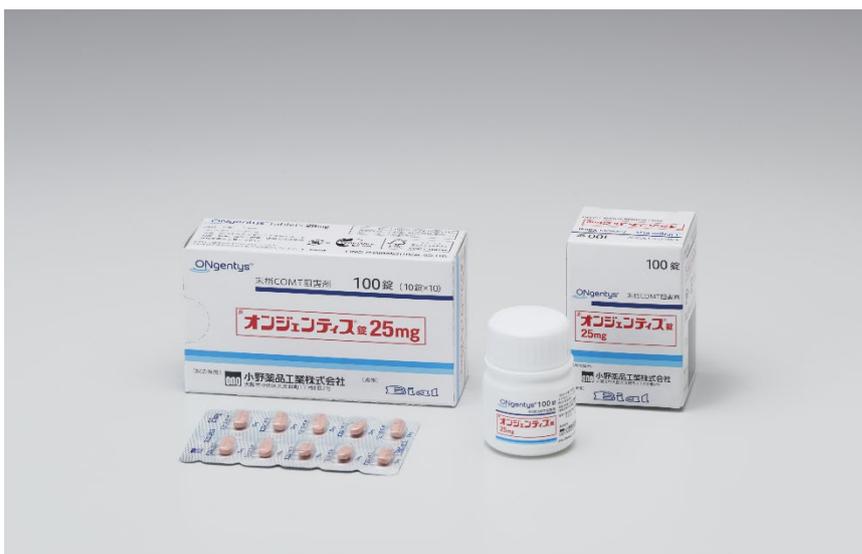
*: Statistics and Information Department, Minister's Secretariat, Ministry of Health, Labour and Welfare. Patient Survey 2014 (Disease and Injury).

Ongentys is a novel long-acting, peripheral COMTi which has demonstrated an efficacy in reducing OFF-time in patients with Parkinson's disease by once-daily treatment with Ongentys. Ongentys is expected to contribute to reducing the burden on patients taking medication as well as improving patient medication adherence.

Overview of Ongentys® Tablets 25 mg

Product name	Ongentys® Tablets 25 mg
Generic name	Opicapone
Indications	Improvement of the end-of-dose motor fluctuations (wearing-off phenomenon) in Parkinson's disease in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride
Dosage and Administration	Opicapone is used in combination with levodopa-carbidopa or levodopa-benserazide hydrochloride. For oral use, the usual adult dosage is 25 mg of opicapone once daily, at least 1 hour before or after administration of levodopa-carbidopa or levodopa-benserazide hydrochloride, and at least 1 hour before or after meal.
Approval date	June 29, 2020
NHI price listing date	August 26, 2020
NHI drug price	¥ 972.00/tablet
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.

Product photograph



About Opicapone (Ongentys® Tablets)

Opicapone is a third-generation catechol-O-methyltransferase (COMT) inhibitor originated at BIAL. It was rationally designed to provide a peripherally selective high COMT inhibitory potency and to avoid cell toxicity. Opicapone increases the bioavailability of levodopa by up to 65% vs placebo¹⁾ and this translates into a reduction in OFF-time in patients with Parkinson's disease and end-of-dose wearing-off^{2,3)}. Molecular structure resulted in a high binding affinity (femtomolar) that translates into a slow complex dissociation rate constant and a long duration of action that allows once-daily dosing^{4,5)}.

In Europe, Opicapone was approved by the European Commission in June 2016 as adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors (DDCis) in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. BIAL has been marketing opicapone under the product name of Ongentys®.

In April 2020, the U.S Food and Drug Administration (FDA) approved opicapone as an add-on treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.

ONO entered into a license agreement for opicapone with BIAL in April 2013, acquiring exclusive development and commercialization rights in Japan

1) : Rocha JF, et al. Br J Clin Pharmacol. 2017;83(3):540-553

2) : Ferreira J et al. Lancet Neurol 2016;15:154–65

3) : Lees A et al. JAMA Neurol. 2017;74(2):197-206

4) : Palma P.N. et al - J Comput Chem 2012 ;33 :970-986.

5) : Rocha JF et al. Br J Clin Pharmacol 2013;76(5):763-775.

Contact

Ono Pharmaceutical Co., Ltd.

Corporate Communications

public_relations@ono.co.jp