

COMPLETE THE SET WITH A SIMPLE ONCE-DAILY CAPSULE¹



Taken once daily at bedtime¹

- Bedtime dosing may enable minimal disruption to patients' daily routines^{1,2}



Works with patients' existing levodopa/DDCI dosing regimens²

- Patients can start ONGENTYS without having to change their current levodopa/DDCI regimens—and ONGENTYS was studied with many levodopa/DDCI formulations²
- Most patients in clinical studies were able to maintain stable levodopa/DDCI dosing through 1 year²



Do not take with food¹

- Patients should not eat food for 1 hour before and at least 1 hour after taking ONGENTYS® (opicapone) capsules¹
- Food reduces absorption. When ONGENTYS was taken with a moderate-fat/moderate-calorie meal, its mean peak plasma concentration decreased by 62% and its mean overall exposure decreased by 31%¹



50-mg standard dose—no need for titration¹

- Patients with moderate hepatic impairment should use a 25-mg capsule, as the mean overall plasma exposure of ONGENTYS increased in these patients^{1,2*}

INDICATION & USAGE

ONGENTYS® (opicapone) capsules is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

ONGENTYS is contraindicated in patients with:

- Concomitant use of non-selective monoamine oxidase (MAO) inhibitors.
- Pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms.

Please see full Important Safety Information on pages 3-4.

*ONGENTYS has not been studied in patients with severe hepatic impairment. Avoid use in these patients.¹

DDCI=dopa decarboxylase inhibitor.

INITIATING ONGENTYS

For patients taking entacapone^{1,3}:

In a clinical trial, when patients taking entacapone in the double-blind period switched to ONGENTYS® (opicapone) capsules in the open-label period...

1. Patients stopped taking entacapone after the last dose of levodopa/DDCI was administered
2. The same day, patients took ONGENTYS at bedtime (without food)
3. The next day, patients continued taking levodopa/DDCI as scheduled and took ONGENTYS once daily at bedtime (without food)

For patients taking other adjunctive treatments^{1,2}:

In clinical trials...

1. Patients took ONGENTYS once daily at bedtime (without food)
2. Patients continued taking their selective MAO-B inhibitors and dopamine agonists as prescribed

DDCI=dopa decarboxylase inhibitor; MAO=monoamine oxidase.

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS & PRECAUTIONS

Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT)

Possible arrhythmias, increased heart rate, and excessive changes in blood pressure may occur with concomitant use of ONGENTYS and drugs metabolized by COMT, regardless of the route of administration (including inhalation).

Monitor patients treated concomitantly with ONGENTYS and drugs metabolized by COMT.

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Falling Asleep During Activities of Daily Living and Somnolence

Patients treated with dopaminergic medications and medications that increase levodopa exposure, including ONGENTYS, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. If a patient develops daytime sleepiness or somnolence, consider discontinuing ONGENTYS or adjusting other dopaminergic or sedating medications and advise patients to avoid driving and other potentially dangerous activities.

Hypotension/Syncope

Monitor patients for hypotension and advise patients about the risk for syncope. If these adverse reactions occur, consider discontinuing ONGENTYS or adjusting the dosage of other medications that can lower blood pressure.

Dyskinesia

ONGENTYS potentiates the effects of levodopa which may result in dyskinesia or exacerbate pre-existing dyskinesia. Reducing the patient's levodopa dosage or the dosage of another dopaminergic drug may reduce dyskinesia that occurs during treatment with ONGENTYS.

Please see Important Safety information continued on the following page.

IMPORTANT SAFETY INFORMATION (CONT'D) WARNINGS & PRECAUTIONS (CONT'D)

Hallucinations and Psychosis

Consider stopping ONGENTYS® (opicapone) capsules if hallucinations or psychotic-like behaviors occur.

Patients with a major psychotic disorder should ordinarily not be treated with ONGENTYS.

Impulse Control/Compulsive Disorders

Patients may experience intense urges (eg, gambling, sexual, spending money, binge eating) and the inability to control them. It is important for prescribers to specifically ask patients or their caregivers about the development of new or increased urges.

Re-evaluate the patient's current therapies for Parkinson's disease and consider stopping ONGENTYS if a patient develops such urges while taking ONGENTYS.

Withdrawal-Emergent Hyperpyrexia and Confusion

A symptom complex resembling neuroleptic malignant syndrome (elevated temperature, muscular rigidity, altered consciousness, and autonomic instability) has been reported in association with rapid dose reduction or withdrawal of drugs that increase central dopaminergic tone. There were no reports

of neuroleptic malignant syndrome in ONGENTYS controlled clinical studies. When discontinuing ONGENTYS, monitor patients and consider adjustment of other dopaminergic therapies as needed.

ADVERSE REACTIONS

The most common adverse reactions (incidence at least 4% and greater than placebo) were dyskinesia, constipation, blood creatine kinase increased, hypotension/syncope, and weight decreased.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call **1-800-FDA-1088**.

Please see ONGENTYS full [Prescribing Information](#).

References: **1.** ONGENTYS [package insert]. San Diego, CA: Neurocrine Biosciences, Inc; 2020. **2.** Data on file. Neurocrine Biosciences, Inc. **3.** Ferreira J, Lees A, Santos A, Hernandez B, Rocha JF, Soares-da-Silva P. How to switch from entacapone to opicapone based on BIPARK-I study experience. Poster presented at: 2017 International Congress of the International Parkinson and Movement Disorder Society (MDS); June 8, 2017; Vancouver, BC.

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Ongentys®
(opicapone) capsules 4