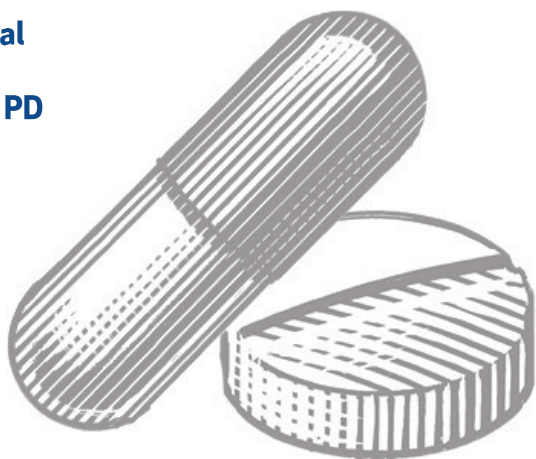




# OPTIMIZE LEVODOPA WITH ONCE-DAILY ONGENTYS<sup>1,2</sup>

**Simple dosing with minimal  
disruption to existing  
routines for patients with PD  
experiencing off time<sup>1,2</sup>**



## **INDICATION & USAGE**

ONGENTYS<sup>®</sup> (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 Important Safety Information throughout and accompanying full [Prescribing Information](#).**

## A SIMPLE ONCE-DAILY CAPSULE, NO TITRATION REQUIRED<sup>1</sup>



### 50-mg standard dose—no need for titration<sup>1</sup>

- Patients with moderate hepatic impairment should use a 25-mg capsule, as the mean overall plasma exposure of ONGENTYS® (opicapone) capsules increased in these patients<sup>1,2\*</sup>



### Taken once-daily at bedtime<sup>1,2</sup>

- Bedtime dosing may enable minimal disruption to patients' daily routines<sup>1,2</sup>



### Works with existing levodopa/DDCI dosing regimens<sup>2</sup>

- Patients can start ONGENTYS without having to change their current levodopa/DDCI regimens—and ONGENTYS was studied with many levodopa/DDCI formulations<sup>2</sup>
- Most patients in clinical studies were able to maintain stable levodopa/DDCI dosing through 1 year<sup>2</sup>



### ONGENTYS should not be taken with food

- Patients should not eat a meal 1 hour before and at least 1 hour after taking ONGENTYS<sup>1</sup>
- 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%<sup>1</sup>

\*ONGENTYS has not been studied in patients with severe hepatic impairment. Avoid use in these patients.<sup>1</sup>

## 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.

#### 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.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#).

## INITIATING ONGENTYS

### For patients taking entacapone<sup>1,3</sup>:

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

- Patients stopped taking entacapone after the last dose of levodopa/DDCI was administered
- The same day, patients took ONGENTYS at bedtime (without food)
- 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<sup>1,2</sup>:

In clinical trials...

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

## IMPORTANT SAFETY INFORMATION (CONT'D)

### WARNINGS & PRECAUTIONS

#### 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.

#### Hallucinations and Psychosis

Consider stopping ONGENTYS 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.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#).



# PERSONALIZED PATIENT SUPPORT SERVICES

- ONGENTYS® (opicapone) capsules is broadly available through any patient-preferred retail pharmacy, including convenient mail order options
- Eligible commercially insured patients may qualify for \$0 copay on their prescriptions, applied automatically for most patients at the pharmacy through the ONGENTYS Savings Program\*
- No cost for eligible patients through the ONGENTYS Patient Assistance Program\*
- CoverMyMeds® is an electronic prior authorization (ePA) solution that helps patients get ONGENTYS and other medications they may need by streamlining the PA process for providers and pharmacists

\*This offer is valid only for patients with commercial (non-government funded) insurance. Additional [terms and conditions](#) apply.

\*Valid only for patients with no insurance or no prescription coverage for ONGENTYS. Additional terms and conditions apply.



Get your patients started with support resources at [ONGENTYSHCP.com](https://www.ongentys.com)

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

### 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](https://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**Please see Important Safety Information throughout and accompanying 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

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