



For people with Parkinson's disease
who are having "Off" episodes

GET MORE OUT OF YOUR LEVODOPA TREATMENT WITH **ONGENTYS**

With less "Off" time and more "Good On" time compared to
immediate-release carbidopa/levodopa alone



Important Information

Approved Use

ONGENTYS® (opicapone) capsules is a prescription medicine used with levodopa and carbidopa in people with Parkinson's disease (PD) who are having "OFF" episodes.

It is not known if ONGENTYS is safe and effective in children.

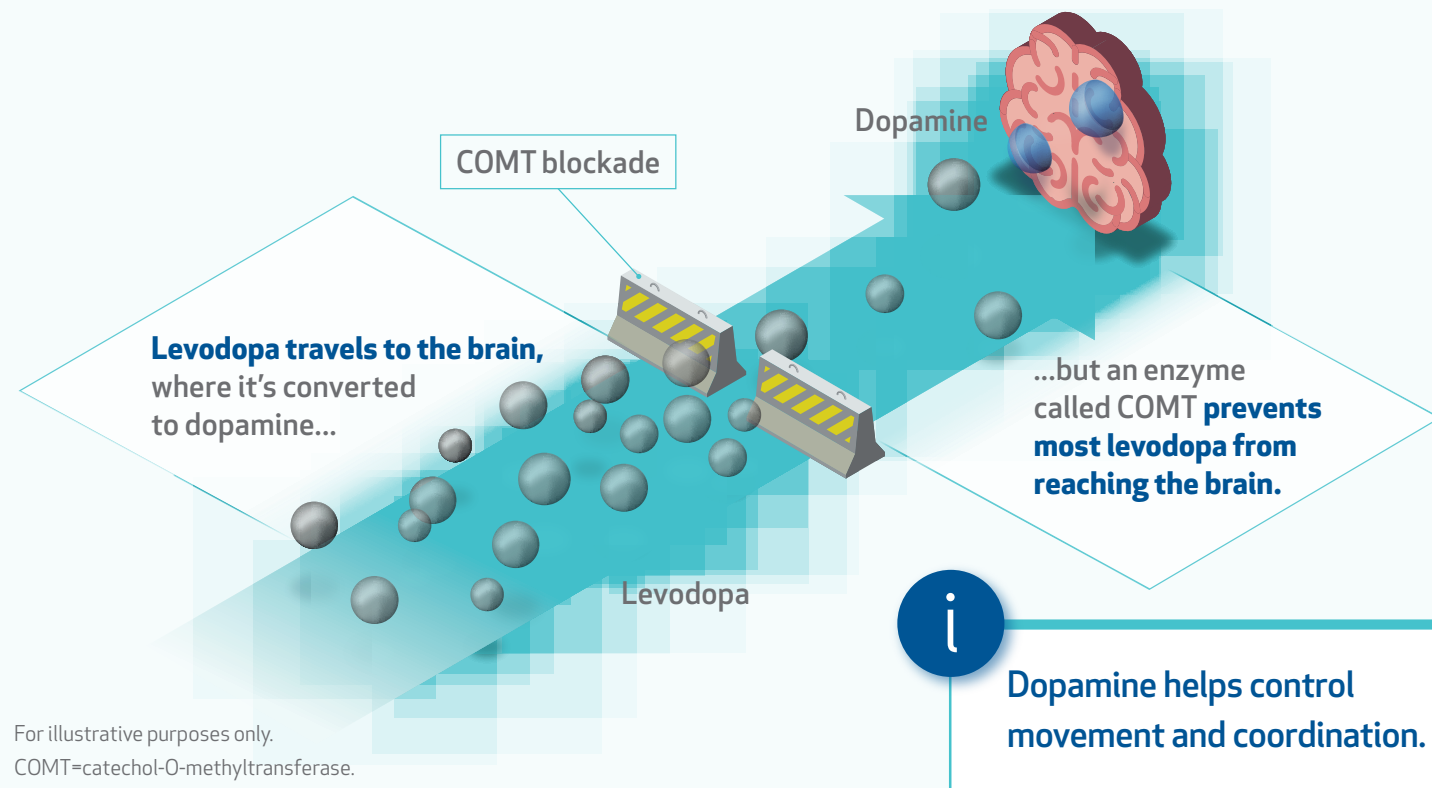
IMPORTANT SAFETY INFORMATION

Do not take ONGENTYS if you:

- take a type of medicine called a non-selective monoamine-oxidase (MAO) inhibitor.
- have a tumor that secretes hormones known as catecholamines.

Please see additional Important Safety Information on other pages and accompanying [full Prescribing Information](#).

LEVODOPA CAN GET BLOCKED

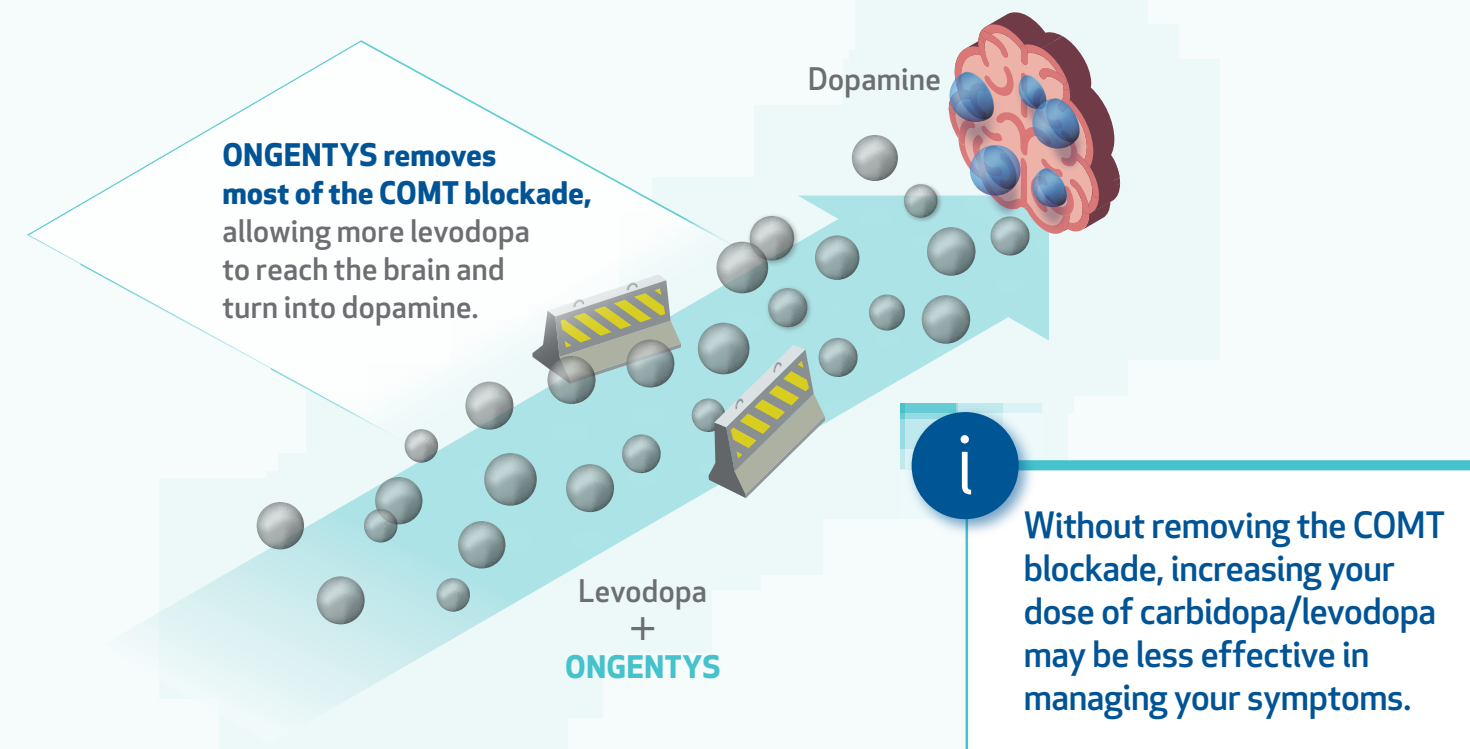


IMPORTANT SAFETY INFORMATION (cont'd)

Before taking ONGENTYS, tell your healthcare provider about all of your medical conditions, including if you:

- have daytime sleepiness from a sleep disorder, have unexpected periods of sleep or sleepiness, or take a medicine to help you sleep or that makes you feel sleepy.
- have had intense urges or unusual behaviors, including gambling, increased sex drive, binge eating, or compulsive shopping.
- have a history of uncontrolled sudden movements (dyskinesia).

ONGENTYS, A COMT INHIBITOR, CLEARS THE WAY



IMPORTANT SAFETY INFORMATION (cont'd)

Before taking ONGENTYS, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- have had hallucinations or psychosis.
- have liver or kidney problems.
- are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Please see additional Important Safety Information on other pages and accompanying [full Prescribing Information](#).

Ongentys®
(opicapone) capsules

ADDING ONGENTYS MAY HELP REDUCE YOUR “OFF” TIME...

ONGENTYS was studied against placebo and entacapone, another COMT inhibitor



Main measurement

Less “Off” time*

with ONGENTYS 50 mg + carbidopa/levodopa
vs 1 hour per day for patients taking carbidopa/levodopa with placebo, **and 1.6 hours per day** for those taking carbidopa/levodopa with entacapone 200 mg[†]

*Change in “Off” time was measured in 2 studies by comparing values at the end of the study (Week 14/15) to baseline. $P=0.002$ for superiority of ONGENTYS + immediate-release carbidopa/levodopa vs immediate-release carbidopa/levodopa + placebo in 1 study and $P=0.008$ in another; $P=0.003$ for noninferiority vs immediate-release carbidopa/levodopa + entacapone.

[†]Entacapone was included in only 1 clinical study.

IMPORTANT SAFETY INFORMATION (cont’d)

Before taking ONGENTYS, tell your healthcare provider about all of your medical conditions, including if you (cont’d):

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take nonselective MAO inhibitors (such as phenelzine, tranylcypromine, and isocarboxazid) or catecholamine medicines (such as isoproterenol, epinephrine, norepinephrine, dopamine, and dobutamine), regardless of how you take the medicine (by mouth, inhaled, or by injection). ONGENTYS and other medicines may affect each other causing side effects. ONGENTYS may affect the way other medicines work, and other medicines may affect how ONGENTYS works.

...AND INCREASE YOUR “GOOD ON” TIME



STUDY 1

AND



STUDY 2

Secondary measurement

More “Good On” time*

with ONGENTYS 50 mg + carbidopa/levodopa
vs 0.8 hours per day for patients taking carbidopa/levodopa with placebo in both studies

*Change in “Good On” time was defined as “On” time without troublesome dyskinesia and measured in 2 studies by comparing values at the end of the study (Week 14/15) to baseline. $P=0.001$ for superiority of ONGENTYS + immediate-release carbidopa/levodopa vs immediate-release carbidopa/levodopa + placebo in 1 study (Week 14/15) and $P=0.065$ (not significant) in another.

IMPORTANT SAFETY INFORMATION (cont’d)

What should I avoid while taking ONGENTYS?

- Do not drive, operate machinery, or do other dangerous activities until you know how ONGENTYS affects you.

Please see additional Important Safety Information on other pages and accompanying [full Prescribing Information](#).



Ongentys®
(opicapone) capsules

ONGENTYS SHOWED A WELL-TOLERATED SAFETY PROFILE

Side effects occurring in at least 2% of people taking ONGENTYS and at a greater frequency than placebo in clinical studies:

ADVERSE REACTION	ONGENTYS 50 MG, % (n=265)	PLACEBO, % (n=257)
Dyskinesia	20	6
Dizziness	3	1
Constipation	6	2
Dry mouth	3	1
Hallucination*	3	1

*Seeing, hearing, or feeling things that are not real.



Most dyskinesia side effects with ONGENTYS (19% out of 20%) were **mild or moderate**. Most dyskinesia occurred during an initial 3-week adjustment period of levodopa.

Side effects occurring in at least 2% of people taking ONGENTYS and at a greater frequency than placebo in clinical studies (cont'd):

ADVERSE REACTION (cont'd)	ONGENTYS 50 MG, % (n=265)	PLACEBO, % (n=257)
Insomnia	3	2
Blood creatine kinase increased	5	2
Weight decreased	4	0
Hypotension/syncope	5	1
Hypertension	3	2

■ Following approval, patients taking ONGENTYS have infrequently reported falls, but it is not clear whether these events were caused by ONGENTYS treatment.

Please see additional Important Safety Information on other pages and accompanying [full Prescribing Information](#).



LOW RATES OF URINE DISCOLORATION AND DIARRHEA

Additional adverse reactions observed in clinical studies:

ADVERSE REACTION	ONGENTYS 50 MG, % (n=265)	PLACEBO, % (n=257)
Urine discoloration	0	0
Diarrhea	2	2
Depressive symptom	0	0
Depressed mood	0	0
Depression	1	1
Impulse control disorders	1	0



People taking ONGENTYS experienced **low rates of urine discoloration and diarrhea** that were comparable to placebo.

Additional adverse reactions observed in clinical studies (cont'd):

ADVERSE REACTION	ONGENTYS 50 MG, % (n=265)	PLACEBO, % (n=257)
Fatigue	2	2
Somnolence	2	2
Sleep attacks and somnolence	2	4
Nausea	3	4
Fall	3	5
Headache	4	5

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Ongentys®
(opicapone) capsules

ONGENTYS FITS INTO YOUR ROUTINE



1 capsule, once a day*

ONGENTYS lasts for 24 hours.[†]

[†]Based on plasma levels in a pharmacokinetic study.

ONGENTYS works with your current carbidopa/levodopa regimen

Talk to your doctor about continuing to take selective MAO-B inhibitors and/or dopamine agonists, as people in clinical trials were able to continue taking these medications as prescribed.



*If you have moderate liver impairment, your doctor should prescribe ONGENTYS at a lower dose.

MAO-B=monoamine oxidase-B.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ONGENTYS?

ONGENTYS may cause serious side effects, including:

- **Falling asleep during normal activities** such as driving a car, talking or eating while taking ONGENTYS or other medicines used to treat Parkinson's disease, without being drowsy or without warning. This may result in having accidents. Your chances of falling asleep while taking ONGENTYS are higher if you take other medicines that cause drowsiness.
- **Low blood pressure or dizziness**, light headedness, or fainting.
- **Uncontrolled sudden movements (dyskinesia)**. ONGENTYS may cause uncontrolled sudden movements or make such movements worse or happen more often.



Taken at bedtime without food

You should not eat food for at least 1 hour before and after taking ONGENTYS.



IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ONGENTYS? (cont'd)

ONGENTYS may cause serious side effects, including (cont'd):

- **Seeing, hearing, or feeling things that are not real (hallucinations), believing things that are not real (delusions)**, or aggressive behavior.
- **Unusual urges (impulse control and compulsive disorders)** such as urges to gamble, increased sexual urges, strong urges to spend money, binge eating, and the inability to control these urges.
Tell your healthcare provider if you experience any of these side effects or notice changes in your behavior.

Please see additional Important Safety Information on other pages and accompanying [full Prescribing Information](#).

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For people with Parkinson's disease who are having "Off" episodes

ASK YOUR DOCTOR ABOUT ONGENTYS



ONGENTYS can optimize your levodopa therapy



ONGENTYS demonstrated a well-tolerated safety profile



ONGENTYS may reduce "Off" time by 2 hours per day vs 1 hour per day with placebo



Simple, once-daily dosing

Take ONGENTYS at bedtime and do not eat food for at least 1 hour before and after.



Scan this QR code for more **ONGENTYS** resources and support.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ONGENTYS? (cont'd)

The most common side effects of ONGENTYS include uncontrolled sudden movements (dyskinesia), constipation, increase in an enzyme called blood creatine kinase, low blood pressure, and weight loss.

These are not all of the possible side effects of ONGENTYS. Call your healthcare provider for medical advice about side effects. 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 additional Important Safety Information on other pages and accompanying [full Prescribing Information](#).



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