

ONGENTYS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using ONGENTYS?

ONGENTYS contains the active ingredient opicapone. ONGENTYS is used to treat symptoms of Parkinson's disease. Parkinson's disease is a progressive disease of the nervous system that causes shaking and affects your movement.

For more information, see Section [1. Why am I using ONGENTYS?](#) in the full CMI.

2. What should I know before I use ONGENTYS?

Do not use if you have ever had an allergic reaction to opicapone or any of the ingredients listed in Section [7. Product details](#) in the full CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ONGENTYS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ONGENTYS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ONGENTYS?

- Take one 50 mg capsule of ONGENTYS once daily or as directed by your doctor.
- Swallow the capsule whole with a glass of water. Take the capsule preferably on an empty stomach (i.e. two hours before or two hours after a meal) and at least one hour before or after taking your levodopa medicine.

More instructions can be found in Section [4. How do I use ONGENTYS?](#) in the full CMI.

5. What should I know while using ONGENTYS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist who treat you that you are using ONGENTYS.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• If you are pregnant, think you may be pregnant or are planning to have a baby while taking this medicine, tell your doctor immediately.• If you are about to have any blood tests, tell your doctor that you are taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not take ONGENTYS to treat any other complaints unless your doctor tells you to.• Do not stop taking your medicine or lower the dosage without checking with your doctor.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• ONGENTYS taken with levodopa may make you feel light-headed, dizzy, or sleepy. Do not drive or operate machinery if you experience any of these side effects.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C. Store in the original package in order to protect from moisture.

For more information, see Section [5. What should I know while using ONGENTYS?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are involuntary and uncontrollable, difficult or painful body movements. Serious side effects include hallucinations, shortness of breath, fainting and increased levels of the enzyme (creatine kinase) in your blood. Many of these side effects can be managed by your doctor adjusting your other medicines.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ONGENTYS

Active ingredient(s): *opicapone (o-pic-a-pone)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ONGENTYS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ONGENTYS.**

Where to find information in this leaflet:

1. [Why am I using ONGENTYS?](#)
2. [What should I know before I use ONGENTYS?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use ONGENTYS?](#)
5. [What should I know while using ONGENTYS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using ONGENTYS?

This medicine is used to treat symptoms of Parkinson's disease and associated movement problems. Parkinson's disease is a progressive disease of the nervous system that causes shaking and affects your movement.

ONGENTYS is for use in adults who are already taking medicines containing levodopa and DOPA decarboxylase inhibitors. It increases the effects of levodopa and helps to relieve the symptoms of Parkinson's disease and movement problems.

Opicapone belongs to a group of medicines called antiparkinsonian/other dopaminergic agents.

Opicapone works to restore the levels of dopamine in the areas of the brain that control movement and coordination. It enhances the effects of another drug, levodopa, commonly used to treat Parkinson's Disease. Opicapone blocks an enzyme that is involved in the breakdown of levodopa in the body, called catechol-O-methyl transferase (COMT). As a result, levodopa remains active for longer time.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

2. What should I know before I use ONGENTYS?

Warnings

Do not take ONGENTYS if you have an allergy to:

- opicapone, or any of the ingredients listed at the end of this leaflet under Section 7. [Product details](#).
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

Do not take ONGENTYS if:

- you have a tumour of the adrenal gland (known as phaeochromocytoma), or of the nervous system (known as paraganglioma), or any other tumour which increase the risk of severe high blood pressure
- you have ever suffered from neuroleptic malignant syndrome which is a rare reaction to antipsychotic medicines;
- you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury;
- you are taking certain antidepressants called monoamine-oxidase (MAO) inhibitors (e.g. phenelzine, tranylcypromine or moclobemide). Ask your doctor or pharmacist if you can take your antidepressant together with ONGENTYS; and
- you are taking linezolid (an antibiotic for the treatment of infections, particularly severe or complicated).

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ONGENTYS is not recommended if you are pregnant. You should use effective contraception if it is possible that you might become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if ONGENTYS passes into human breast milk. As the risk to babies/infants cannot be excluded you must stop breastfeeding while taking ONGENTYS.

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take ONGENTYS:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- suffer from loss of appetite, or weight loss
- feel weakness, or exhaustion within a short period of time.

Your doctor may need to reconsider your treatment.

Tell your doctor if:

You or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm you or others. These behaviours are called 'impulse control disorders' and can include: addictive gambling, an abnormally high sex drive or an increased preoccupation with sexual thoughts or feelings. Behaviours such as these have been reported in patients using other medicines for Parkinson's disease.

Your doctor may need to review your treatments.

ONGENTYS contains lactose. If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

ONGENTYS contains residues of sulfites which may rarely cause severe hypersensitivity reactions and bronchospasm.

ONGENTYS contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

If you have not told your doctor about any of the above, tell him/her before you start taking ONGENTYS.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

ONGENTYS will be administered with other medicines containing levodopa and DOPA decarboxylase inhibitors.

Read the notice of these medicines carefully.

Some medicines and ONGENTYS may interfere with each other. These include:

- medicines for depression or anxiety such as venlafaxine, maprotiline or desipramine. Taking ONGENTYS with these medicines may increase the risk of side effects. Your doctor may need to adjust your treatment;
- Safinamide used for Parkinson's disease. There is no experience taking ONGENTYS and safinamide together. Your doctor may need to adjust your treatment;
- medicines to treat asthma such as rimiterole or isoprenaline. ONGENTYS may increase their effect;
- medicines used to treat allergic reactions such as adrenaline. ONGENTYS may increase their effect;
- medicines used to treat heart failure such as dobutamine, dopamine or dopexamine. ONGENTYS may increase their effects;
- medicines containing quinidine, a medicine used to treat abnormal heart rhythms or malaria. Taking ONGENTYS and quinidine together, i.e. at the same time, may decrease the effect of ONGENTYS.
- medicines containing warfarin, a medicine used to thin the blood. ONGENTYS may reduce the plasma levels of warfarin.

These medicines may be affected by ONGENTYS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I use ONGENTYS?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The recommended dose is 50 mg once daily. Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, ONGENTYS may not work as well and your problem may not improve.

How to take ONGENTYS

ONGENTYS is for oral use.

Take ONGENTYS at least one hour before or after taking your levodopa medicine.

Swallow the capsule whole with a glass of water. ONGENTYS shall be taken preferably on an empty stomach (i.e. two hours before or two hours after a meal).

Do not change the prescribed dose on your own. Talk to your doctor or pharmacist if you think the effect of this medicine is too low or too strong.

The dose of other medicines to treat Parkinson's disease may need to be adjusted when you start taking ONGENTYS. Follow the instructions that your doctor has given you

When to take ONGENTYS

Take ONGENTYS preferably at bedtime.

How long to take ONGENTYS

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Do not stop taking ONGENTYS unless your doctor tells you to as your symptoms may get worse.

If you stop taking ONGENTYS your doctor may need to adjust the dose of other medicines that you are taking to treat Parkinson's disease.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to take ONGENTYS

If you forget to take one dose, you should continue the treatment and take the next dose as scheduled.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much ONGENTYS (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ONGENTYS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Take the medicine package and this leaflet with you. This will help the doctor identify what you have taken.

5. What should I know while using ONGENTYS?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ONGENTYS.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

Do not take ONGENTYS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how ONGENTYS affects you.

This medicine may influence reactions, and the ability to drive and use tools or machines. ONGENTYS taken with levodopa may make you feel light-headed, dizzy, or sleepy.

Do not drive or operate machinery if you experience any of these side effects.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Looking after your medicine

Store in the original package to protect from moisture.

If you take the capsules out of the blister pack, they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store ONGENTYS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ONGENTYS.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Side effects caused by ONGENTYS are usually mild to moderate and occur mostly within the first five weeks of treatment. Some side effects may be caused by the increased effects of using ONGENTYS together with levodopa. Many of the side effects can be managed by your doctor adjusting your levodopa medicine.

It is very common to experience involuntary and uncontrollable, or difficult or painful body movements when taking ONGENTYS.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
General well-being related <ul style="list-style-type: none"> difficulty falling or staying asleep sleepiness sleep disorder high or low blood pressure dry mouth urinary tract infection weight loss loss of appetite strange dreams feeling low in energy or tired having falls difficulty in concentration 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.
Coordination related <ul style="list-style-type: none"> feeling unsteady 	

<ul style="list-style-type: none"> shaking dizziness involuntary and uncontrollable, excessive, difficult or painful body movements 	
Other symptoms <ul style="list-style-type: none"> increased levels of triglycerides (fats) in your blood increased levels of the enzyme (creatinine kinase) in your blood depression anxiety nightmares headache dry eye blocked ear a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting pain or swelling of the abdomen abnormal colour of urine need to wake and pass urine at night 	
Stomach/digestion related <ul style="list-style-type: none"> constipation feeling sick (nausea) vomiting (being sick) diarrhoea indigestion 	
Pain related <ul style="list-style-type: none"> muscle spasm muscle twitching, stiffness, or pain pain in arms or legs 	

Serious side effects

Serious side effects	What to do
General well-being related <ul style="list-style-type: none"> experiencing, seeing or hearing things which do not exist (hallucinations) shortness of breath fainting 	Tell your doctor as soon as possible if you notice any of these serious side effects.
Coordination related <ul style="list-style-type: none"> Parkinson's disease 	

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

Some of these side effects (e.g. increased levels of triglycerides or the enzyme creatine kinase in your blood, or high or low blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Ischemic heart disease (diseases of the arteries with insufficient blood supply to the heart) have been frequently observed when using other substances with the same mechanism of action as opicapone (inhibition of COMT).

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ONGENTYS contains

Active ingredient (main ingredient)	Each ONGENTYS capsule contains 50 mg opicapone
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• sodium starch glycollate type A• pregelatinised maize starch• magnesium stearate• gelatin• indigo carmine aluminium lake• erythrosine• titanium dioxide• shellac• propylene glycol• ammonia solution, concentrated• simethicone

Do not take this medicine if you are allergic to any of these ingredients.

What ONGENTYS looks like

ONGENTYS 50 mg hard capsules are dark blue, imprinted "OPC 50" on the cap and "Bial" on the body.

Each ONGENTYS 50 mg hard capsules pack contains 10, 30 or 90 capsules (AUST R 321017).

Not all pack sizes may be marketed.

Who distributes ONGENTYS

Manufacturer

BIAL - Portela & C^a, S.A.
À Av. da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal

Sponsor

Maxx Pharma Pty Ltd
Level 20, 181 William Street
Melbourne, VIC, 3000
Australia

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