

ORIDOPA 100/25 TM

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.

1. Why am I using ORIDOPA 100/25?

ORIDOPA 100/25 contains the active ingredients levodopa and carbidopa. ORIDOPA 100/25 is used to treat the symptoms of Parkinson's disease.

For more information, see Section [1. Why am I using ORIDOPA 100/25?](#) in the full CMI.

2. What should I know before I use ORIDOPA 100/25?

Do not use if you have ever had an allergic reaction to levodopa, carbidopa or any of the ingredients listed at the end of the 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 ORIDOPA 100/25?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ORIDOPA 100/25 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 ORIDOPA 100/25?

The usual starting dose is one ORIDOPA 100/25 mg tablet taken three times a day. Your doctor will then adjust this dose depending on the severity of your condition and your response to treatment.

More instructions can be found in Section [4. How do I use ORIDOPA 100/25?](#) in the full CMI.

5. What should I know while using ORIDOPA 100/25?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ORIDOPA 100/25.• If you become pregnant, tell your doctor immediately. You should not take this medicine while you are pregnant.• If you experience times where ORIDOPA 100/25 does not appear to be working as well as it did previously, tell your doctor• Visit your doctor regularly so they can check on your progress.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or reduce the dose suddenly without talking to your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking ORIDOPA 100/25 until you know how it affects you. This medicine may cause dizziness, light-headedness or sleepiness.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C in the original container. Protect from light.

For more information, see Section [5. What should I know while using ORIDOPA 100/25?](#) in the full CMI.

6. Are there any side effects?

Common side effects: nausea (feeling sick), vomiting, diarrhoea, pain in the stomach, constipation, dizziness, light-headedness, extreme sleepiness and sudden onset of sleep and unusual and uncontrollable twitching, jerking or writhing movements, muscle and/or joint pain.

Severe side effects: compulsive behaviours, confusion, chest pain/tightness, shortness of breath or difficulty breathing and fast or irregular heartbeats.

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.

ORIDOPA 100/25™

Active ingredients: *levodopa and carbidopa (as monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ORIDOPA 100/25. **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 ORIDOPA 100/25.**

Where to find information in this leaflet:

- [1. Why am I using ORIDOPA 100/25?](#)
- [2. What should I know before I use ORIDOPA 100/25?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ORIDOPA 100/25?](#)
- [5. What should I know while using ORIDOPA 100/25?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ORIDOPA 100/25?

ORIDOPA 100/25 contains the active ingredients levodopa and carbidopa. ORIDOPA 100/25 is an anti-Parkinson medicine containing dopaminergic agents that work together to increase the level of dopamine in the brain.

ORIDOPA 100/25 is used to treat some of the symptoms of Parkinson's disease. ORIDOPA 100/25 is most helpful in improving slow movement and muscle stiffness. It is also frequently helpful in treating shaking, difficulty in swallowing and drooling.

Parkinson's disease is a disorder of the nervous system. It is caused by a lack of dopamine, a natural substance that is produced in the brain. Dopamine relays messages in the part of the brain that controls muscle movement.

Other medicines can also help to treat this condition.

2. What should I know before I use ORIDOPA 100/25?

Warnings

Do not use ORIDOPA 100/25 if:

- you are allergic to levodopa, carbidopa, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are taking a medicine called a monoamine oxidase inhibitor (MAOI) such as phenelzine and tranylcypromine, which can be used to treat depression.
- you have unusual skin lumps or moles which have not been examined by your doctor, or if you have ever had skin cancer or melanoma.

- you have a type of glaucoma called narrow-angle glaucoma.
- you are pregnant or breastfeeding.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Check with your doctor if you:

- have depression or mental disturbances
- have heart disease, including irregular heart beat, also known as arrhythmia
- have kidney problems
- have liver problems
- have hormonal problems
- have lung problems including asthma
- have convulsions or fits
- have a type of glaucoma called wide angle glaucoma
- you have ever had a serious condition called neuroleptic malignant syndrome (NMS), with symptoms such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure
- have any other medical conditions
- take any medicines for any other condition
- you have previously been or are currently being treated with levodopa
- have allergies to any other medicines, foods, dyes or preservatives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take ORIDOPA 100/25 if you are pregnant. Tell your doctor immediately if you become pregnant. There is not enough information to recommend using ORIDOPA 100/25 during pregnancy.

Do not take ORIDOPA 100/25 if you are breastfeeding or plan to breastfeed. One of the active ingredients of ORIDOPA 100/25 passes into breast milk. Therefore, because of the potential harm to the baby, ORIDOPA 100/25 should not be used during breastfeeding.

Use in children under 18 years

ORIDOPA 100/25 should not be used in children under the age of 18 years. The safety of ORIDOPA 100/25 and how well it works has not been studied in children younger than 18 years of age.

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.

Some medicines may interfere with ORIDOPA 100/25 and affect how it works. These include:

- monoamine oxidase inhibitor (MAOI) such as phenelzine and tranylcypromine. Taking ORIDOPA 100/25 together with some, but not all, MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know whether or not the MAOI medicine you are taking can be safely taken with ORIDOPA 100/25.
- dopamine D2 receptor antagonists such as phenothiazines, butyrophenones and risperidone
- some antibiotics such as erythromycin, rifampicin, ampicillin and chloramphenicol
- apomorphine, a medicine used in Parkinson's Disease.
- some medicines used to treat high blood pressure
- other medicines for Parkinson's disease
- some medicines for depression
- some medicines for psychiatric disorders
- methyl dopa, a medicine for high blood pressure
- isoniazid, a medicine used to treat tuberculosis
- phenytoin, a medicine used to treat convulsions
- papaverine, a medicine used to expand blood vessels to treat men with erectile dysfunction
- medicines containing iron, such as iron tablets or multiple vitamins.

You may need to take a different amount of your medicines or to take different medicines while you are taking ORIDOPA 100/25. Your doctor and pharmacist have more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ORIDOPA 100/25.

4. How do I use ORIDOPA 100/25?

How much to take

- Your doctor will tell you how many tablets to take each day. The dose varies considerably from patient to patient.
- The usual starting dose is one 100/25 mg tablet taken three times a day. Your doctor will then adjust this dose depending on the severity of your condition, your response to treatment and whether you are taking other medicines.
- The maximum dose is 8 tablets each day
- Follow the instructions provided and use ORIDOPA 100/25 until your doctor tells you to stop.

How to take ORIDOPA 100/25

- ORIDOPA 100/25 should be taken with a glass of water.

If you forget to use ORIDOPA 100/25

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you use too much ORIDOPA 100/25

If you think that you have used too much ORIDOPA 100/25, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ORIDOPA 100/25?

Things you should do

- If you experience times where ORIDOPA 100/25 does not appear to be working as well as it did previously, tell your doctor.
- If you become pregnant, tell your doctor immediately. You should not take this medicine while you are pregnant.
- Before having any surgery or other hospital treatment, tell the anaesthetist or the doctor that you are taking ORIDOPA 100/25. It may cause unwanted side effects if you take it at the same time as some medicines that are used in hospital.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ORIDOPA 100/25.
- Be sure to keep all of your doctor's appointments so that your progress can be checked. Your doctor may also want to take some tests from time to time to help prevent unwanted side effects.
- Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of ORIDOPA 100/25 and other medicines used to treat Parkinson's disease (known as dopamine dysregulation syndrome).
- Tell your doctor if you or your family/caregiver 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 yourself or others. These behaviours are called impulse control disorders and

can include addictive gambling, excessive eating or spending, an abnormally high sex drive or a preoccupation with an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Remind any doctor, dentist or pharmacist you visit that you are using ORIDOPA 100/25.

Things you should not do

- Do not stop using this medicine or reduce the dose suddenly without consulting your doctor. It may be necessary to reduce the dose of ORIDOPA 100/25 gradually in order to prevent side effects.
- Do not give this medicine to anyone else, even if their condition seems similar to yours.
- Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

- **If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.** These symptoms may be a sign of low blood pressure. You can usually prevent them by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.
- **Be careful not to eat a diet high in protein.** The amount of levodopa absorbed by the body may be impaired if you eat a diet high in protein. Ask your doctor, pharmacist or dietician to check your diet.

Driving or using machines

Be careful before you drive, use any machines or tools or doing jobs that require you to be alert until you know how ORIDOPA 100/25 affects you.

This medicine may cause dizziness, light-headedness or sleepiness. Very rarely it can cause extreme sleepiness and sudden onset of sleep in the middle of daytime activities, sometimes without warning. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Looking after your medicine

- Keep your medicine in the original container until it is time to take it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach, bowel or urinary related <ul style="list-style-type: none"> • nausea (feeling sick) or vomiting • indigestion • diarrhoea • pain in the stomach • constipation • dark coloured urine 	Speak to your doctor if you have any of these less serious side effects and they worry you.
Motion or movement related <ul style="list-style-type: none"> • dizziness or light-headedness • spinning sensation (vertigo) • aches and pains • muscle cramps and pain or joint pain • unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements • shakiness • twitching or spasm of the eyelids 	
Mental states or behaviour related <ul style="list-style-type: none"> • difficulty sleeping or unusual dreams • feeling depressed or agitated • unsteadiness when walking, or a lack of coordination in your movements or speech • extreme sleepiness or sudden onset of sleep in the middle of daytime activities 	
Eye related <ul style="list-style-type: none"> • blurred vision • seeing double 	
Others <ul style="list-style-type: none"> • dry mouth • headache • increased sweating • weight gain or loss 	

Serious side effects

Serious side effects	What to do
<p>Allergy related</p> <ul style="list-style-type: none"> • rash, itching or hives on the skin • swelling of the face, lips, mouth, throat or tongue • difficulty breathing <p>Mental states or behaviour related</p> <ul style="list-style-type: none"> • worsening of your symptoms of Parkinson's disease • confusion or hallucinations (seeing, hearing or feeling things that are not there) • craving for large doses of ORIDOPA 100/25 in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe uncontrolled movements (dyskinesias), mood swings, or other side effects after taking large doses of ORIDOPA 100/25. • inability to resist the impulse to perform an action that could be harmful, which may include: <ul style="list-style-type: none"> ○ strong impulse to gamble excessively ○ altered or increased sexual interest and behaviour of significant concern to your or to others ○ uncontrolled excessive shopping or spending, ○ binge eating or compulsive eating ○ medicine use or repetitive purposeless activities. <p>Heart or blood pressure related</p> <ul style="list-style-type: none"> • chest pain • fast or irregular heartbeats, also called palpitations <p>Signs of possible anemia (low amount of iron in your blood)</p> <ul style="list-style-type: none"> • tiredness, headaches, shortness of breath when exercising, dizziness and looking pale <p>Signs of possible liver problems</p> <ul style="list-style-type: none"> • loss of appetite, feeling generally unwell, fever, itching, yellow colour to the skin and eyes • <p>Stomach, bowel or urinary related</p> <ul style="list-style-type: none"> • gastrointestinal bleeding 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<p>(coughing up blood or blood in the stools)</p> <ul style="list-style-type: none"> • diarrhoea, usually with blood and mucus • strong urge to urinate that cannot be delayed, which is followed by a sharp pain or burning sensation in the urethra when the urine is released (urinary tract infection) • blood in the urine <p>Others</p> <ul style="list-style-type: none"> • symptoms of neuroleptic malignant syndrome, such as a sudden increase in body temperature, sweating, fast heart beat, muscle stiffness and fluctuating blood pressure • temporary paralysis or weakness of muscles • signs of melanoma, such as new skin spots or changes to the size, shape, colour or edges of an existing skin spot, freckle or mole. • fainting 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 ORIDOPA 100/25 contains

Active ingredients (main ingredients)	<ul style="list-style-type: none"> • levodopa 100 mg • carbidopa 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • maize starch • mannitol • croscarmellose sodium • povidone • magnesium stearate

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

What ORIDOPA 100/25 looks like

ORIDOPA 100/25 are white or off-white, round, uncoated tablets debossed with “LC 100” and a score line on one side and plain on the other. (AUST R 427013).

ORIDOPA 100/25 tablets are supplied in HDPE bottles with a polypropylene child resistant closure containing 100 tablets.

Who distributes ORIDOPA 100/25

Orion Pharma (Aus) Pty Limited
Level 24, Tower 3, 300 Barangaroo Avenue
Sydney NSW 2000, Australia
Telephone: 1800 861 913

This leaflet was prepared in September 2024.