

Sinadopa

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 this medicine?

This medicine contains the active ingredient levodopa and carbidopa monohydrate. This medicine is used to treat some of the symptoms of Parkinson's disease.

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

2. What should I know before I use this medicine?

Do not use if you have ever had an allergic reaction to this medicine 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 this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with this medicine 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 this medicine?

- Your doctor will tell you how many tablets to take each day. Follow all directions given to you by your doctor carefully.
- Swallow the levodopa/carbidopa tablet whole or as half tablets, with a glass of water.

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

5. What should I know while using this medicine?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using this medicine.• If you notice times where this medicine does not appear to be working as well as it did previously, tell your doctor.• If you notice any changes in your own health, or if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist as soon as possible.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or lower the dosage, without checking with your doctor.• Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful when driving or operating machinery until you know how this medicine affects you.• This medicine may cause dizziness or light-headedness in some people.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the original package until it is time to take them.• Store in a cool, dry place where the temperature stays below 25°C.• Keep it where children cannot reach it.

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

6. Are there any side effects?

The most common side effects are nausea, hallucinations, confusion, dizziness, abnormal uncontrolled movements and dry mouth.

Serious side effects include blood in the urine, difficult or painful urination, changes in mood, forgetfulness, signs of anaemia such as tiredness and shortness of breath, frequent or worrying infections, bruising or bleeding, fainting, skin changes, numbness or tingling in the feet.

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.

Sinadopa

Active ingredient(s): *levodopa and carbidopa monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. **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 this medicine.**

Where to find information in this leaflet:

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

1. Why am I using this medicine?

This medicine contains two active ingredients **levodopa and carbidopa monohydrate**.

Levodopa is a chemical closely related to dopamine which allows the body to make its own dopamine. Carbidopa makes sure that enough levodopa gets to the brain where it is needed. In many patients, levodopa/carbidopa reduces some of the symptoms of Parkinson's disease.

This medicine is used to treat some of the symptoms of Parkinson's disease.

This is a disease of the nervous system that mainly affects body movement. The three main symptoms are shaking (tremor), muscle stiffness and slow and unsteady movement. People with Parkinson's disease often walk with a shuffle as they have difficulty in initiating movement. If untreated, Parkinson's disease can cause difficulty in performing normal daily activities.

This medicine is most helpful in improving slow movement and muscle stiffness. It is also frequently helpful in treating shaking, difficulty in swallowing and drooling.

The symptoms of Parkinson's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. Dopamine relays messages in the part of the brain that controls muscle movement. When too little dopamine is produced, slowness of movement results.

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

2. What should I know before I use this medicine?

Warnings

Do not use this medicine if:

- you are allergic to levodopa or carbidopa, or any of the ingredients listed at the end of this leaflet.** 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 skinAlways check the ingredients to make sure you can use this medicine.
- you have any 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**
- are being treated for depression with certain medicines called Monoamine Oxidase Inhibitors (MAOIs).** Ask your doctor or pharmacist if you are not sure whether you are taking one of these medicines.
- you are breast-feeding or plan to breast-feed.** It has been shown that levodopa/carbidopa passes into breast milk and there is a possibility that your baby may be affected. Therefore, this medicine should not be used during breast-feeding.
- the packaging is torn or shows signs of tampering.**
- the expiry date on the pack has passed.** If you take this medicine after the expiry date has passed, it may not work. 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.

Do not give this medicine to a child or teenager under the age of 18, unless advised by the child's doctor.

The safety and effectiveness in children and teenagers under 18 years of age has not been established.

Tell your doctor if you:

- are pregnant or intend to become pregnant or are breastfeeding.** Your doctor will discuss the possible risks and benefits involved.
- you have or have had any medical conditions, especially the following:**
 - depression or mental disturbances

- heart disease, including irregular heartbeat, also known as arrhythmia
- lung disease, including asthma
- kidney, liver or hormonal problems
- convulsions or fits
- glaucoma
- peptic ulcer disease
- **you or your family member/caregiver notices you are developing urges to gamble, increased sexual urges, excessive eating, spending or medicine use, repetitive purposeless activities with other medicines for Parkinson's Disease, and/or other intense urges that could harm yourself or others.**
These behaviours are called impulse control disorders. Your doctor may need to review your treatments.
- **you have previously been or are currently being treated with levodopa.**
- **you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you take this medicine.

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

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

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

It has been shown that one of the active ingredients of this medicine passes into breast milk. Therefore, because of the potential harm to the baby, this medicine should not be used during breast-feeding.

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 this medicine and affect how it works. These include:

- some medicines used to treat high blood pressure
- some medicines used to treat depression
- some medicines used to treat psychiatric problems
- some medicines used to treat diseases related to involuntary movements
- some medicines used to treat muscle spasms
- phenytoin, a medicine used to treat convulsions
- isoniazid, a medicine used to treat tuberculosis
- selegiline, another medicine used to treat Parkinson's disease
- iron supplements and multivitamins containing iron.

These medicines may be affected by levodopa/carbidopa or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect this medicine.

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

4. How do I use this medicine?

How much to take

- **Take this medicine only when prescribed by your doctor.**

Your doctor will tell you how many tablets to take each day. This depends on the severity of your condition, your response to treatment and whether you are taking other medicines. 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 adjust this dose depending on the severity of your condition, your response to treatment and whether you are taking other medicines.

- **Follow all the instructions given to you by your doctor carefully.**

They may differ from the information contained in this leaflet.

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

When to take this medicine

- **Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take this medicine

- **Swallow the tablets, whole or as half tablets (only if told by your doctor), with a glass of water.**

How long to take this medicine

- **Continue taking this medicine for as long as your doctor prescribes.**

This medicine helps control some of your symptoms of Parkinson's disease but does not cure it. Therefore, it must be taken every day. It is important to keep taking your medicine even if you feel well.

- **Do not stop taking this medicine, or lower the dosage, without checking with your doctor.**

Your doctor may want you to gradually reduce the amount of this medicine you are using before stopping completely. This may help reduce the possibility of withdrawal symptoms such as muscle stiffness, fever and mental changes.

If you forget to use this medicine

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.

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

This may increase the chance of you getting an unwanted side effect.

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 of this medicine (overdose)

If you think that you or anyone else may have taken too much of this medicine, 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 this medicine?

Things you should do

- **If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.**
You may feel light-headed or dizzy while taking this medicine. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from the bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, tell your doctor.
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**
Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- **If you experience times where this medicine does not appear to be working as well as it did previously, tell your doctor.**
After taking this medicine for long periods of time, such as a year or more, some people suddenly lose the ability to move. This loss of movement may last from a few minutes to several hours. The person is then able to move as before. This condition may unexpectedly occur again and again.

This problem is called the "on-off" effect. Your doctor may prescribe you a stronger dose of levodopa/carbidopa or may ask you to take it more frequently. Your doctor may need to prescribe you a different medicine.

- **Have blood tests when your doctor says to make sure this medicine is not causing any problems with your blood, liver, kidneys or heart.**
- **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.
- **If you plan to have surgery that needs a general anaesthetic, tell your doctor, dentist, surgeon or anaesthetist that you are taking this medicine.**
It may affect other medicines used during surgery.
- **If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**
- **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.
- **If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.**
Levodopa/Carbidopa may cause false test results with some urine sugar tests.
- **Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time (such as blood tests to check your blood, liver, kidneys or heart), to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- **Do not give this medicine to anyone else, even if they have the same condition as you.**
- **Do not take this medicine 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.**
If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as muscle stiffness, fever or mental changes. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how this medicine affects you.

This medicine may cause dizziness or light-headedness in some people. Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be

dangerous. Children should be careful when riding bicycles or climbing trees.

In addition, in very rare cases, levodopa/carbidopa may cause excessive sleepiness and sudden onset of sleep. If you experience these effects, do not drive or operate machinery until these effects have resolved.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

Keep your tablets in the original package until it is time to take them.

If you take the tablets out of the original package, they may not keep well.

Store it below 25°C in a cool dry place 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.

Heat and dampness can damage some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the tablets have passed their expiry date, ask your pharmacist what to do with any 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 this medicine.

This medicine helps most people with Parkinson's disease, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time, they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

These are possible side effects of this medicine. For the most part, these have been mild.

Less serious side effects	What to do
<ul style="list-style-type: none"> • abnormal uncontrolled movements, including muscle twitching or spasms, which may or may not resemble your 	<p>Speak to your doctor if you have any of</p>

<p>Parkinson's symptoms</p> <ul style="list-style-type: none"> • feeling sick (nausea), vomiting, loss of appetite • dizziness or light-headedness when standing quickly • dry mouth • discolouration of urine, sweat and/or saliva • urinary tract infection which often presents as a strong urge to urinate accompanied by pain or burning during urination • dream abnormalities • sleepiness or sudden onset of sleep • slow movements • twitching or spasm of the eyelids • hair loss • diarrhoea • tingling, numbness, pain or burning sensation in the feet and/or hands. 	<p>these side effects and they worry you.</p>
<ul style="list-style-type: none"> • You may experience an inability to resist the impulse to perform an action that could be harmful, which may include: <ul style="list-style-type: none"> ○ strong impulses to gamble ○ increased sexual drive ○ uncontrollable excessive shopping or spending ○ binge/compulsive eating ○ taking medicines and repetitive purposeless activities ○ other urges 	<p>Tell your doctor if you experience any of these behaviours.</p>

Serious side effects

These are all serious side effects that need urgent medical attention. Serious side effects are generally rare.

Serious side effects	What to do
<ul style="list-style-type: none"> • blood in the urine • difficult or painful urination • changes in mood such as depression • forgetfulness • signs of anaemia, such as tiredness, being short of breath, and looking pale • signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers • bruising or bleeding more easily than normal, nose bleeds • fainting • skin rash, itchiness • pinkish, itchy swellings on the skin, also called hives or nettle rash 	<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>

<ul style="list-style-type: none"> numbness or tingling in the hands or feet 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. bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea vomiting blood or material that looks like coffee grounds chest pain fast or irregular heartbeats, also called palpitations muscle stiffness accompanied by fever mental changes such as feeling very fearful or paranoid, hallucinations symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, mouth, throat, tongue or other parts of the body; rash, itching or hives on the skin 	
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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 this medicine contains

Active ingredient (main ingredient)	250/25 mg tablet: <ul style="list-style-type: none"> levodopa 250 mg carbidopa (as monohydrate) 25 mg 100/25 mg tablet: <ul style="list-style-type: none"> levodopa 100 mg carbidopa (as monohydrate) 25 mg
Other ingredients	<ul style="list-style-type: none"> crospovidone microcrystalline cellulose

(inactive ingredients)	<ul style="list-style-type: none"> magnesium stearate pregelatinised maize starch indigo carmine aluminium lake (250/25 strength only) quinolone yellow aluminium lake (100/25 strength only)
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Do not take this medicine if you are allergic to any of these ingredients.

What this medicine looks like

250/25 mg strength:

Round, light blue uncoated tablets with 'C' on one side and '20' on the other side. AUST R 275983.

100/25 mg strength:

Round, light yellow uncoated tablets with 'C' on one side and '19' on the other side. AUST R 275974.

The tablets are supplied in Alu/Alu blister packs of 100 tablets.

Who distributes this medicine

Arrotex Pharmaceuticals Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121
Australia

Web: www.arrotex.com.au

This leaflet was prepared in January 2024.