

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 SINEMET?

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

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

2. What should I know before I use SINEMET?

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

3. What if I am taking other medicines?

Some medicines may interfere with SINEMET 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 SINEMET?

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

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

5. What should I know while using SINEMET?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SINEMET.• If you notice times where SINEMET 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 taking SINEMET, or lower the dosage, without checking with your doctor.• Do not give SINEMET 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 SINEMET affects you.• SINEMET 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 bottle until it is time to take them.• Store in a cool, dry place where the temperature stays below 30°C• Keep it where children cannot reach it

For more information, see Section [5. What should I know while using SINEMET?](#) 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.

SINEMET

Active ingredient(s): *levodopa and carbidopa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SINEMET. **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 SINEMET.**

Where to find information in this leaflet:

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

1. Why am I using SINEMET?

SINEMET contains the active ingredient levodopa and carbidopa.

SINEMET 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.

SINEMET 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.

SINEMET contains two active ingredients, levodopa and carbidopa. 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, SINEMET reduces some of the symptoms of Parkinson's disease.

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

2. What should I know before I use SINEMET?

Warnings

Do not use SINEMET if:

- you are allergic to SINEMET, 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 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 (MAO) inhibitors.**

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 one of the active ingredients of SINEMET passes into breast milk. Therefore, because of the potential harm to the baby, SINEMET 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 you are not sure whether you should start taking SINEMET, talk to your doctor.

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

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

Tell your doctor if you:

- **you are pregnant or intend to become pregnant.**
Your doctor will discuss the possible risks and benefits of using SINEMET during pregnancy.
- **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 or spending, medicine use or 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 any SINEMET.

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 SINEMET passes into breast milk. Therefore, because of the potential harm to the baby, SINEMET 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 SINEMET 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 SINEMET, or may affect how well the tablets work. You may need different amounts of your medicine, 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 SINEMET.

4. How do I use SINEMET?

How much to take

- **Take SINEMET 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 directions 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.**

How to take SINEMET

- **Swallow SINEMET whole or as half tablets, with a glass of water.**

For SINEMET 250/25, the score-line on the tablets is for dividing the tablets into smaller doses.

How long to take SINEMET

- SINEMET helps control some of your symptoms of Parkinson's disease, but does not cure it. Therefore SINEMET must be taken every day. Continue taking SINEMET for as long as your doctor prescribes.
- **Do not stop taking SINEMET, or lower the dosage, without checking with your doctor.**

Your doctor may want you to gradually reduce the amount of SINEMET 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 SINEMET

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 that you missed.

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

If you take too much SINEMET (overdose)

If you think that you or anyone else may have taken too much SINEMET, 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 SINEMET?

Things you should do

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

Although rare, you may feel light-headed or dizzy while taking SINEMET. 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, tell your doctor and pharmacist that you are taking SINEMET.**
- **If you experience times where SINEMET 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 SINEMET 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 SINEMET is not causing any problems with your blood, liver, kidneys or heart.**
- **If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking SINEMET.**
- **If you become pregnant while taking SINEMET, tell your doctor.**
- **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.**

SINEMET may cause false test results with some urine sugar tests.

Things you should not do

- **Do not give SINEMET to anyone else, even if they have the same condition as you.**

Driving or using machines

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

SINEMET may cause dizziness or light-headedness in some people. Make sure you know how you react to SINEMET before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

In addition, in very rare cases, SINEMET 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 bottle until it is time to take them.**

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

- **Store SINEMET below 30°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 SINEMET or the tablets have passed their expiry date, ask your pharmacist what to do with any that are 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 SINEMET.

SINEMET 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.

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

Less serious side effects

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

Less serious side effects	What to do
<ul style="list-style-type: none"> • abnormal uncontrolled movements, which may or may not resemble your Parkinson's symptoms • feeling sick (nausea), vomiting, loss of appetite • dizziness, 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 	<p>Speak to your doctor if you have any of 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 ○ and/or 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 	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • 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. • Swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing • 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 call palpitations • Muscle stiffness accompanied by fever • Mental changes such as feeling very fearful or paranoid, hallucinations • Shortness of breath, difficulty breathing 	

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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 SINEMET contains

250/25 mg tablet

Active ingredient (main ingredient)	<ul style="list-style-type: none"> levodopa 250 mg carbidopa 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> maize starch microcrystalline cellulose magnesium stearate pregelatinised maize starch indigotine

100/25 mg tablet

Active ingredient (main ingredient)	<ul style="list-style-type: none"> levodopa 100 mg carbidopa 25 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> maize starch microcrystalline cellulose magnesium stearate pregelatinised maize starch quinoline yellow

None of the SINEMET tablets contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

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

What SINEMET looks like

SINEMET 250/25

Light, dappled blue, oval-shaped tablet with '654' and a scoreline on one side and plain on the other.

(AUST R 319331)

SINEMET 100/25

Yellow, oval-shaped tablet with '650'.

(AUST R 319330)

All bottles of SINEMET tablets contains 100 tablets.

Who distributes SINEMET

Organon Pharma Pty Ltd

Building A,

26 Talavera Road

MACQUARIE PARK

NSW 2113

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