

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SINEMET. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SINEMET against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SINEMET is used for

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.

Before you take SINEMET

When you must not take it

Do not take SINEMET if:

- **you have an allergy to SINEMET or any of the ingredients listed at the end of this leaflet**
- **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 years, 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.

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant**
Your doctor will discuss the possible risks and benefits of using SINEMET during pregnancy.
2. **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
3. **you or your family member/caregiver notices you are developing urges to gamble, 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.**
4. **you have previously been or are currently being treated with levodopa.**
5. **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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and SINEMET may interfere with each other. 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
- 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SINEMET.

How to take 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. 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.

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 it

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

For SINEMET 100/25, the score-line on the tablets is not for dividing the tablets into smaller doses and should not be used that way. If you must divide a tablet to help you swallow it, make sure you have all of the tablet pieces (the full dose). If you do not have all the pieces, throw them away and take another tablet from the bottle.

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

How long to take it

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 take it

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 (overdose)

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

While you are using SINEMET

Things you must 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 SINEMET. This is because your blood pressure is falling suddenly. 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, 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 taken 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.

Things you must not do

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

Things to be careful of

Be careful when driving or operating machinery 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. If you drink alcohol, dizziness or light-headedness may be worse.

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.

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.

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.

Tell your doctor if you notice any of the following and they worry you:

- abnormal uncontrolled movements including muscle twitching or spasms, which may or may not resemble your Parkinson's symptoms
- dizziness, light-headedness when standing quickly
- feeling sick (nausea), vomiting, loss of appetite
- 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

Tell your doctor if you experience any of these behaviours:

You may experience an inability to resist the impulse to perform an action that could be harmful, which may include:

- strong impulses to gamble
- increased sexual drive
- uncontrollable excessive shopping
- spending, binge/compulsive eating
- taking medicines and repetitive purposeless activities
- and/or other urges

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

Tell your doctor immediately if you notice any of the following:

- 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
- 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.

These are serious side effects. You may need urgent medical attention. Serious side effects are generally rare.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:

- 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 called palpitations
- muscle stiffness accompanied by fever
- mental changes such as feeling very fearful or paranoid, hallucinations
- shortness of breath, difficulty breathing

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using SINEMET

Storage

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.

Keep SINEMET in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it 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.

Disposal

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.

Product description

You may be prescribed any ONE of the following:

1) SINEMET 250/25

AUST R NUMBER: 319331

What it looks like

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

Ingredients

Active ingredients:

SINEMET - 250 mg levodopa and 25 mg carbidopa per tablet.

Inactive ingredients:

- maize starch
- microcrystalline cellulose
- magnesium stearate
- pregelatinised maize starch
- indigotine

2) SINEMET 100/25

AUST R NUMBER: 319330

What it looks like

Yellow, oval-shaped tablet with '650' and a score line on one side and plain on the other.

Ingredients

Active ingredients:

SINEMET 100/25 - 100 mg levodopa and 25 mg carbidopa per tablet.

Inactive ingredients:

- maize starch
- microcrystalline cellulose
- magnesium stearate
- pregelatinised maize starch
- quinoline yellow

All bottles of SINEMET tablets contain 100 tablets.

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

Supplier

SINEMET is supplied in Australia by:

Organon Pharma Pty Ltd
Building A
26 Talavera Road
MACQUARIE PARK
NSW 2113

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