

SINEMET CR[®]200/50

Levodopa-Carbidopa

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SINEMET CR 200/50. 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 CR 200/50 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 CR 200/50 is used for

SINEMET CR 200/50 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 CR 200/50 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 CR 200/50 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. SINEMET CR 200/50 is formulated to slowly release the levodopa and carbidopa. This keeps the amount of levodopa in your brain as even as possible. In many patients, SINEMET CR 200/50 reduces some of the symptoms of Parkinson's disease.

Your doctor may have prescribed SINEMET CR 200/50 for another reason. Ask your doctor if you have any questions about why SINEMET CR 200/50 has been prescribed for you.

Before you take SINEMET CR 200/50

When you must not take it

Do not take SINEMET CR 200/50 if:

- **you have an allergy to SINEMET CR 200/50 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 CR 200/50 passes into breast milk. Therefore, because of the potential harm to the baby, SINEMET CR 200/50 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 CR 200/50, talk to your doctor.

Do not give SINEMET CR 200/50 to a child or teenager below the age of 18, unless advised by the child's doctor.

The safety and effectiveness of SINEMET CR 200/50 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 CR 200/50 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, 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.

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 CR 200/50.

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 CR 200/50 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
- 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 CR 200/50, 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 CR 200/50.

How to take SINEMET CR 200/50

How much to take

Take SINEMET CR 200/50 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. Most patients need 2-8 tablets per day, taken in divided doses.

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 CR 200/50 whole, with a glass of water.

Do not break the tablets.

Do not chew or crush the tablets.

If the tablets are crushed or chewed, they will no longer have their slow-release properties.

How long to take it

SINEMET CR 200/50 helps control some of your symptoms of Parkinson's disease, but does not cure it. Therefore SINEMET CR 200/50 must be taken every day. Continue taking SINEMET CR 200/50 for as long as your doctor prescribes.

Do not stop taking SINEMET CR 200/50, or lower the dosage, without checking with your doctor.

Your doctor may want you to gradually reduce the amount of SINEMET CR 200/50 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 CR 200/50. Do this even if there are no signs of discomfort or poisoning.

While you are using SINEMET CR 200/50

Things you must 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 CR 200/50. 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 CR 200/50.

If you experience times where SINEMET CR 200/50 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 CR 200/50 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 CR 200/50 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 CR 200/50.

If you become pregnant while taking SINEMET CR 200/50, tell your doctor.

Things you must not do

Do not give SINEMET CR 200/50 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 CR 200/50 affects you.

SINEMET CR 200/50 may cause dizziness or light-headedness in some people. Make sure you know how you react to SINEMET CR 200/50 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 CR 200/50 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 CR 200/50 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 CR 200/50.

SINEMET CR 200/50 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, 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
- dream abnormalities, sleeping difficulty
- sleepiness or sudden onset of sleep
- hallucinations
- weakness
- confusion
- flushing
- hair loss

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 or spending
- binge/compulsive eating
- taking medicines and repetitive purposeless activities
- and/or other urges

Most of these are the more common side effects of SINEMET CR 200/50. For the most part, these have been mild.

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

- 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

- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- chest pain
- fast or irregular heartbeats, also called palpitations
- it becomes impossible to empty your bladder (urinary retention)
- mental changes such as feeling very fearful or paranoid, hallucinations
- muscle stiffness accompanied by fever
- 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 CR 200/50

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 CR 200/50 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 CR 200/50 or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

SINEMET CR 200/50

AUST R NUMBER: 326195

What it looks like

SINEMET CR 200/50 comes as a peach-coloured, oval shaped, biconvex tablet, deep scored on one side and the other marked '521'.

A bottle of SINEMET CR 200/50 contains 100 tablets.

Ingredients

Active ingredients:

- SINEMET CR 200/50 - 50 mg carbidopa and 200 mg levodopa per tablet.

Inactive ingredients:

- hyprolose
- magnesium stearate
- VA/Crotonates copolymer
- quinoline yellow aluminium lake
- ferric oxide

SINEMET CR 200/50 tablets do not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Supplier

SINEMET CR 200/50 is supplied in Australia by:

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

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