SINEMET CR®

Carbidopa/Levodopa
50/200 mg tablet

What is in this leaflet

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

SINEMET CR 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 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 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 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 reduces some of the symptoms of Parkinson's disease.

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

Before you take SINEMET CR

When you must not take it

Do not take SINEMET CR if:

- you have an allergy to SINEMET CR 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 inhibitors (MAOI). 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. Levodopa, one of the components of SINEMET CR, is passed into human milk.
- 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, talk to your doctor.

Use in children

Do not give SINEMET CR to a child or teenager below the age of 18, unless advised by the child's doctor. The safety and effectiveness of SINEMET CR 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 during pregnancy.
2. you have or have had any medical conditions, especially the following:
   - depression or mental disturbances
   - heart disease, including irregular heart beat, 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, 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.

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 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 or multivitamins containing iron

These medicines may be affected by SINEMET CR, 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.

How to take SINEMET CR

How much to take

Take SINEMET CR 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 tablets whole, with a glass of water.

In order to maintain the slow-release properties of SINEMET CR, do not chew or crush the tablets.

How long to take it

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

Do not stop taking SINEMET CR, or lower the dosage, without checking with your doctor. Your doctor may want you to gradually reduce the amount of SINEMET CR 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 National Poisons Centre (telephone 0800 POISON or 0800 764 766), 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. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers of these places handy.

While you are using SINEMET CR

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. 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 CR.

If you experience times where SINEMET CR 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 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 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.

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

Things you must not do

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

Things to be careful of

Be careful driving or operating machinery until you know how SINEMET CR affects you. SINEMET CR may cause dizziness or light-headedness in some people. Make sure you know how you react to SINEMET CR 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.

SINEMET CR can cause somnolence (excessive drowsiness) and sudden sleep onset episodes. Therefore you must refrain from driving or engaging in activities where impaired alertness may put yourself or others at risk of injury or death (e.g. operating machines) until such recurrent episodes 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 may cause false test results with some urine sugar tests.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SINEMET CR.

SINEMET CR helps most people with Parkinson's disease, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse 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 (also called 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, sleeping difficulty
- sleepiness or sudden onset of sleep
- weakness
- confusion
- flushing
- hair loss

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, and/or other urges. Tell your doctor if you experience any of these behaviours:

These are the more common adverse effects of SINEMET CR. 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
- seizures

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

Other adverse 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 adverse effects. You may not experience any of them.

After using SINEMET CR

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

Product description

SINEMET CR

What it looks like

SINEMET CR comes as a peach coloured, oval-shaped tablet, deep score on one side with '521' on the other.
A bottle of SINEMET CR contains 100 tablets.

Ingredients

Active ingredients:

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

Inactive ingredients:

- hyprolose
- magnesium stearate
- crotonic acid-polyvinylacetate copolymer
- iron oxide red
- quinolone yellow.

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

Supplier

SINEMET is supplied in New Zealand by:

Organon (New Zealand) Limited
Level 7, 36 Brandon Street
Wellington 6100
Tel: 0800 111 700

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