

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

SINEMET CR® Tablets

Carbidopa and Levodopa

Read all of this leaflet carefully before you start taking SINEMET CR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SINEMET CR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT SINEMET CR CONTAINS

Each tablet of SINEMET CR contains 50 mg carbidopa and 200 mg levodopa as the active ingredients.

In addition, SINEMET CR contains the following inactive ingredients: hydroxypropyl cellulose, magnesium stearate, polyvinyl acetate crotonic acid co-polymer, red ferric oxide, quinoline yellow aluminium lake.

Sugar free.

SINEMET CR is a combination of carbidopa, an aromatic amino acid decarboxylase inhibitor and levodopa, the metabolic precursor of dopamine in a controlled-released tablet. It treats the symptoms of Parkinson's disease.

2. WHAT SINEMET CR IS USED FOR

Your doctor has prescribed SINEMET CR to treat the symptoms of Parkinson's disease.

Parkinson's disease is a chronic disorder characterised by slow and unsteady movement, muscular stiffness and tremor. If untreated, Parkinson's disease can cause difficulty in performing normal daily activities.

HOW DOES SINEMET CR TREAT PARKINSON'S DISEASE?

SINEMET CR tablets are formulated to slowly release the two active ingredients, levodopa and carbidopa.

It is believed that the symptoms of Parkinson's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. Dopamine has the role of relaying messages in certain regions of the brain that control muscle movement. Difficulty in movement results when too little dopamine is produced.

Levodopa acts to replenish dopamine in the brain, while carbidopa ensures that enough levodopa gets to the brain where it is needed. In many patients, this reduces the symptoms of Parkinson's disease.

3. BEFORE YOU TAKE SINEMET CR

Do not take SINEMET CR if you:

- are allergic to any of its ingredients

- have any suspicious skin lesions (moles) which have not been examined by your doctor or if you have ever had skin cancer
- are being treated for depression with certain MAO inhibitor drugs
- have narrow-angle glaucoma.

Tell your doctor or healthcare professional before taking SINEMET CR

Tell your doctor about any medical problems you have or have had including: allergies, depression or mental disturbance, lung, kidney, liver, heart or hormonal problems, peptic ulcer disease, convulsions or glaucoma.

Let your doctor know if you have previously been treated with levodopa.

Tell your doctor if 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.

Take special care with SINEMET CR

Use in children

Use of SINEMET CR by patients below the age of 18 is not recommended.

Pregnancy and breastfeeding

It is not known what effect SINEMET CR may have on human pregnancy. Levodopa, one of the components of SINEMET CR, is passed into human milk. If you are pregnant, may become pregnant or intend to breastfeed, tell your doctor, who will help you weigh the benefits of the medicine against possible hazards.

Driving and using machinery

Individual responses to medication may vary. Certain side effects that have been reported with SINEMET CR may affect some patients ability to drive or operate machinery (see **POSSIBLE SIDE EFFECTS**).

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 and somnolence have resolved.

Taking other medicines with SINEMET CR

Although SINEMET CR can generally be given with other medicines, there are exceptions. Your doctor may warn against use with certain medications used to treat psychiatric conditions or mental depression, iron or iron supplements, tuberculosis, high blood pressure, muscle spasms, convulsions or other diseases related to involuntary movements.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE SINEMET CR

Do not share medicines prescribed for you with any other person.

Always take SINEMET CR exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

The dosage of SINEMET CR is variable and your doctor will adjust it according to the severity of your disease and your response to treatment.

If so prescribed, the SINEMET CR tablets may be broken in half. In order to maintain the slow-release properties of SINEMET CR, do not chew or crush the tablets.

For best results take SINEMET CR every day. It is important to carefully follow your doctor's advice on how much SINEMET CR to take and how often to take it. Promptly inform your doctor of any change in your condition such as nausea or abnormal movements, as this may require an adjustment in your prescription.

Do not stop taking this medicine abruptly, unless advised to do so by your doctor.

If you take more SINEMET CR than you should

If you take too many tablets, contact your doctor or pharmacist immediately so that medical attention may be given promptly. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take or missed a dose of SINEMET CR

Try to take SINEMET CR as prescribed. However, if you have missed a tablet, take it as soon as you remember. If it is almost time to take your next tablet, do not take the missed tablet, but resume your normal schedule.

Effect when treatment with SINEMET CR is stopped

Do not stop taking SINEMET CR or lower the dosage without checking with your doctor. A group of symptoms may occur including: muscle stiffness, fever and mental changes.

5. POSSIBLE SIDE EFFECTS

Not all side effects reported for SINEMET CR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The most frequent side effects are: abnormal movements (which may or may not resemble your Parkinson's symptoms), nausea, hallucinations, confusion, dizziness and dry mouth.

Other possible side effects include: abnormal dreams or difficulty sleeping, sleepiness, sudden sleep onset episodes, mental changes, depression, weakness, vomiting and loss of appetite, flushing, hair loss, fainting and discolouration of urine, sweat, and/or saliva and melanoma.

You may also 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.

Hypersensitivity reactions may occur such as hives, itching, rash and swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing or swallowing. Contact your doctor immediately if these symptoms occur.

Your doctor or pharmacist has a more complete list of side effects. Some of these may be serious. If you experience any unusual symptoms, inform your doctor or seek medical attention immediately.

HOW CAN I LEARN MORE ABOUT SINEMET CR?

You may obtain further information from your doctor or pharmacist. Both have full prescribing information about SINEMET CR.

6. STORING AND DISPOSING OF SINEMET CR

Do not use this medicine after the month and year following EXP.: on the container.

Store at or below 25 °C. Protect from light.

Keep SINEMET CR in the original container and keep the container tightly closed.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF SINEMET CR

SINEMET CR Tablets are supplied in bottles of 100.

8. IDENTIFICATION OF SINEMET CR

SINEMET CR Tablet is a peach, oval-shaped tablet, deep score on one side, 521 on the other side.

9. REGISTRATION NUMBER

Y/5.4.1/279

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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