

SINEMET[®] CONTROLLED RELEASED TABLET

Carbidopa/levodopa (50/200 mg)

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What SINEMET CR is used for

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

Why has my doctor prescribed SINEMET CR?

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

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

How SINEMET CR works

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. The controlled release formula keeps the amount of levodopa in your body as even as possible.

Before you use SINEMET CR

- When you must not use it

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 medicines
- have narrow-angle glaucoma

- Before you start to use it

Tell your doctor about any medical conditions you have or have had including:

- Allergies
- Depression or other mental problems;
- Lung, kidney, liver, or hormonal problems;
- Heart attack, heart beat problems, circulation or breathing problems
- Ulcer in your gut (called 'duodenal' or 'peptic

ulcer') or have vomited blood

- History of fits (convulsions);
- Or glaucoma
- You are due to have surgery

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

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Sinemet CR.

Tell your doctor if you or your family/care giver notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive, or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Use in children

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

Use in women who are pregnant or breast-feeding

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 breast-feed, tell your doctor, who will help you weigh the benefits of the medication against possible hazards.

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- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Sinemet can affect the way some other medicines work. Also some other medicines can affect the way Sinemet CR works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for Parkinson's disease (e.g. levodopa, selegiline)
- Medicines for high blood pressure
- Medicines for depression (e.g. monoamine oxidase inhibitors (MAOI), Tricyclic antidepressants)
- Medicines to treat low iron
- Medicines for mental disorder (e.g., phenothiazines, butyrophenones and risperidone)
- Medicine for tuberculosis (e.g. isoniazid)
- Medicines for seizure (e.g. Phenytoin)
- Papaverine, which is used to treat impotence in men.

Your doctor or pharmacist has a more complete list of medicines to avoid while taking SINEMET CR. Tell your doctor about all medicines you are taking or plan to take, including those obtained without prescription.

How to use SINEMET CR

- How much to use

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.

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

- When to use it

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.

- How long to use it

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

- If you forget to use it

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.

- If you use too much (overdose)

If you take too many tablets, contact your doctor immediately so that medical attention may be given promptly.

While you are using SINEMET CR

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking SINEMET CR.
- Tell your doctor immediately if you become

pregnant while taking this medication.

- Things you must not do

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

- Things to be careful of

May I drive or operate machinery while using SINEMET CR?

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 "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.

Side effects

SINEMET CR is generally well tolerated. Like any medicine, however, SINEMET CR may have unintended or undesirable effects known as side effects.

- The most frequent side effects are: abnormal movements (which may or may not resemble your Parkinson's symptoms),

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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, discoloration of urine, sweat, and/or saliva, and melanoma (skin cancer).
- 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 behaviors.
- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by

calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

How can I learn more about SINEMET CR?

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

Storage and Disposal of SINEMET CR

- Storage

- SINEMET CR should be kept below 30°C. Keep SINEMET CR in the original container and keep the container closed tightly and protected from light and moisture.
- Keep SINEMET CR and all medicines out of the reach of children.
- Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Dappled, purple-colored, oval shaped tablet, plain on one side and the other side is engraved with '521'.

SINEMET CR is available in packing of 100 tablets.

- Ingredients

Active ingredient: SINEMET CR (carbidopa, levodopa) is a Sustained Release Tablets. Each tablet contains carbidopa and levodopa as the active ingredients in the following strengths: SINEMET CR 50/200 contains carbidopa 50 mg and levodopa 200 mg.

Inactive ingredients:

Hydroxypropyl Cellulose, Magnesium Stearate, Hypromellose, FD&C Blue #2 and FD&C Red #40.

- MAL number

MAL12125048ACRZ

Product Manufacturer

Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
Morgantown, West Virginia
26505
USA

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.
T2-9, Jaya 33, No. 3 (Lot 33)
Jalan Semangat, Seksyen 13
46100 Petaling Jaya, Selangor,
Malaysia.

Date of revision

23/03/2016 (version 022016)

Serial Number:

BPFK(R4/2)230316/00092