PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

SINEMET CR® Tablets

Carbidopa and Levodopa

Sugar free

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, pharmacist or other health care provider.
- 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.

What is in this leaflet:

1 What SINEMET CR is and what it is used for

2 What you need to know before you take SINEMET CR

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4 Possible side effects

5 How to store SINEMET CR

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1. What SINEMET CR is and it 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-released tablet.

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.

2. .What you need to know before you take SINEMET CR

Do not take SINEMET CR if you:

- if you are hypersensitive (allergic) to carbidopa or levodopa or any of the other ingredients of SINEMET CR (listed in section 6)
- 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.

Warnings and precautions

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/carer notices you are developing addiction-like symptoms leading to craving for large doses of Sinemet CR and other medicines used to treat Parkinson's disease.

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.

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.

This is because SINEMET CR can affect how other medicines work. Also, some other medicines can affect the way SINEMET CR works.

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

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 or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

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.

3. 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. If you have the impression that the effect of SINEMET CR is too strong or too weak, tell your doctor or pharmacist.

Do not stop taking this medicine abruptly, unless advised to do so by your doctor.
Your doctor will tell you how long your treatment with SINEMET CR will last.

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 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. Do not take a double dose to make up for forgotten individual doses.

If you stop taking SINEMET CR

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.

4. Possible Side effects

SINEMET CR can have 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 SINEMET CR, please consult your doctor, pharmacist or other healthcare provider for advice.

The most common side effects are:

- Abnormal movements including twitching or spasms (which may or may not resemble your Parkinson's symptoms)
- Nausea
- Urinary tract infections (frequency: very common)
- Hallucinations
- Confusion
- Dizziness
- 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
- discolouration of urine, sweat and/or saliva
- melanoma (changed patches of pigmented skin, including, irritated or irregular moles, or moles in which you have noticed changes).

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.

Craving for large doses of Sinemet CR in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of Sinemet CR.

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.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SINEMET CR.

You can also report any side effects directly to Organon's Pharmacovigilance Unit at dpoc.zaf@organon.com or Tel: +27 (0) 10 344 0706.

5. How to store 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).

6.Contents of the pack and other information

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.

What SINEMET CR looks like and contents of the pack

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

SINEMET CR Tablets are supplied in bottles of 100.

Holder of Certificate of Registration

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