

PART III: CONSUMER INFORMATION



levodopa and carbidopa tablets, USP

This leaflet is part III of a three-part "Product Monograph" published when SINEMET[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SINEMET[®]. Contact your physician or pharmacist if you have any questions about the drug.

Remember – This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other people, nor use it for any other condition.**

ABOUT THIS MEDICATION

SINEMET[®] is the brand name for the substance – levodopa and carbidopa, available **only on prescription** from your physician.

What the medication is used for:

Your physician has prescribed SINEMET[®] 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.

What it does:

SINEMET[®] is a combination of levodopa, the metabolic precursor of dopamine, and carbidopa, an aromatic amino acid decarboxylase inhibitor. It treats the symptoms of Parkinson's disease.

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.

When it should not be used:

Do not take SINEMET[®], if you:

- are allergic to any of its ingredients
- have any suspicious skin lesions (moles) which have not been examined by your physician or if you have ever had skin cancer
- are being treated with certain MAO inhibitor drugs, such as for depression, within the last 2 weeks
- have narrow-angle glaucoma
- have untreated heart, liver, kidney, lung, blood or hormonal disease
- have been told that you should not take sympathomimetic drugs such as isoproterenol, amphetamines, epinephrine or cough and cold medications containing drugs related to epinephrine

What the medicinal ingredients are:

Levodopa and carbidopa

What the non-medicinal ingredients are:

Croscopovidone, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, pregelatinized starch.

SINEMET[®] 250/25 tablets also contain FD&C Blue No. 2 Aluminum Lake. SINEMET[®] 100/25 tablets also contain D & C yellow No. 10 Lake.

What dosage forms it comes in:

Tablets (levodopa/carbidopa): 100 mg/25 mg (yellow), and 250/25 (light dapple-blue).

WARNINGS AND PRECAUTIONS

Some people feel sleepy, drowsy, or, rarely, may suddenly fall asleep without warning (i.e. without feeling sleepy or drowsy) when taking SINEMET[®]. During treatment with SINEMET[®] take special care when you drive or operate a machine. If you experience excessive drowsiness or a sudden sleep onset episode, refrain from driving and operating machines, and contact your physician.

Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known if this problem is associated with Parkinson's disease or the drugs used to treat Parkinson's disease. Therefore, patients treated with SINEMET[®] should have periodic skin examinations.

BEFORE taking SINEMET[®], tell your physician or pharmacist if you:

- have or have had any medical conditions including: allergies; depression or mental disturbances; lung, kidney, liver, heart or hormonal problems; skin cancer or suspicious skin lesions; ulcer in your gut (called "duodenal" or "peptic ulcer"); convulsions/seizures; or glaucoma
- have previously been treated with levodopa
- are pregnant or plan to become pregnant
- are breastfeeding or wish to breastfeed
- are going to have an operation that requires general anesthesia
- drive or operate machinery

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 behaviors are called impulse control disorders. Your doctor may need to review your treatments.

It is not recommended to use SINEMET[®] while you are pregnant or breast-feeding.

It is not known what effect SINEMET[®] may have on human pregnancy. Levodopa, one of the components of SINEMET[®], is passed into human milk. If you are pregnant, may become pregnant or intend to breast-feed, tell your physician, who will help you weigh the benefits of the drug for you against possible risks to your baby. As you improve on SINEMET[®], you may increase your physical activity gradually and with caution related to any other medical conditions you may have.

SINEMET[®] should not be given to children under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

Although SINEMET[®] can generally be given with other medicines, there are exceptions. Tell your physician about all medicines you are taking or plan to take, including those obtained without a prescription.

It is particularly important to tell your physician if you are taking:

- antihypertensive drugs (used to treat elevated blood pressure)
- some medications used to treat psychiatric conditions or mental depression (including phenothiazines, butyrophenones, risperidone, selegiline, tricyclic antidepressants and monoamine oxidase inhibitors)
- tetraabenazine (medication used to treat conditions related to involuntary movements such as Huntingtons Disease)
- phenytoin (anti-epileptic medication)
- papaverine (medication for intestinal spasms)
- isoniazid (medication to treat tuberculosis)
- metoclopramide (for nausea and vomiting)
- iron salts (such as multivitamins tablets) which may reduce the amount of carbidopa and/or levodopa available to the body

A change in diet to foods that are high in protein (such as meat, fish, dairy products, seeds and nuts) may delay the absorption of levodopa and SINEMET[®] may not work as well as it should.

PROPER USE OF THIS MEDICATION

Usual dose:

The dosage of SINEMET[®] is variable and your physician will adjust it according to the severity of your disease and your response to treatment.

SINEMET[®] is an immediate-release formulation of levodopa-carbidopa that is designed to begin release of ingredients within 30 minutes. For best results take SINEMET[®] every day. It is important to carefully follow your physician's advice on how much SINEMET[®] to take and how often to take it. Promptly inform your physician of any change in your condition such as nausea or abnormal movements, as this may require an adjustment in your prescription.

Do not change the dose regimen prescribed by your physician and do not add any additional antiparkinson medications, including other levodopa-carbidopa preparations, without first consulting your physician.

Do not stop taking this medicine abruptly or lower the dosage without checking with your physician. If you suddenly stop or reduce your dosage you may experience the following symptoms: stiff muscles, high temperature (fever) and mental changes.

Overdose:

In case of an overdose, contact your physician immediately so that medical attention may be given promptly.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Missed Dose:

Try to take SINEMET[®] as prescribed. However, if you have missed a dose, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

SINEMET[®] is generally well tolerated. Like any other medicine, however, SINEMET[®] may have unintended or undesirable effects, so called side-effects.

Very rare but serious side effects that have been reported include sudden sleep onset episodes (see WARNINGS AND PRECAUTIONS).

Certain side effects that have been reported with SINEMET[®] may affect some patients' ability to drive or operate machinery.

SINEMET[®] 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 (see WARNINGS AND PRECAUTIONS).

The most frequent side effects are: abnormal movements including twitching or spasms (which may or may not resemble your Parkinson's symptoms), and nausea.

Other possible side effects include: mental changes, dream abnormalities, hair loss, diarrhea, dizziness, vomiting, loss of appetite, and slow movement (see WARNINGS AND PRECAUTIONS). Occasionally, dark colour (red, brown or black) may appear in your saliva, urine or sweat after you take SINEMET[®].

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptoms / Effects | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|--------------------|---|-------------------------------------|--------------|---|
| | | Only if severe | In all cases | |
| Most Common | Abnormal involuntary movements, such as spasms or twitching | | ✓ | |
| Common | Hallucinations (seeing or hearing things that are not there) | | ✓ | |
| Rare | Allergic reactions [red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing or swallowing] | | | ✓ |
| | Excessive sleepiness; Falling asleep without warning | | ✓ | |
| | Impulse control symptoms (inability to resist the impulse to perform an action that could be harmful) such as compulsive gambling, increased sexual urges, and/or behaviours, uncontrollable excessive shopping or spending, binge/ compulsive eating, and/or other urges | | ✓ | |
| | Changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes (melanoma) | | ✓ | |
| | Uneven (irregular) heart beat or palpitations | | ✓ | |
| | Feeling of lightheaded-ness as when standing quickly | | ✓ | |

This is not a complete list of side effects. For any unexpected effects while taking SINEMET[®], contact your doctor or pharmacist.

HOW TO STORE IT

Store your tablets at room temperature (15 °C–30 °C). Store in tightly closed container, protected from light and moisture.

Keep all medicines out of the reach of children.

Do not use outdated medicine.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or

Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about SINEMET[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the [Health Canada website](http://www.healthcanada.gc.ca) or Merck Canada web site www.merck.ca or by calling Merck Canada at 1-800-567-2594

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