

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SINEMET**[®]

levodopa and carbidopa tablets, USP

Read this carefully before you start taking **SINEMET**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SINEMET**[®].

Serious Warnings and Precautions

You can suddenly fall asleep without any warning while taking **SINEMET**[®].

You should not:

- drive
- use machines or
- take part in activities that require you to be alert.

You may put yourself and others at risk for serious injury or death.

If this happens to you, contact your doctor **right away**.

Falling asleep suddenly without warning has also been reported in patients taking other similar drugs to treat Parkinson's disease.

What is **SINEMET[®] used for?**

SINEMET[®] is used to treat the symptoms of Parkinson's disease in adults.

How does **SINEMET[®] work?**

SINEMET[®] contains two ingredients:

- Levodopa: this acts to replenish dopamine in the brain
- Carbidopa: ensures that enough levodopa gets to the brain where it is needed.

It is believed that the symptoms of Parkinson's disease are caused by a lack of dopamine. Dopamine is a naturally occurring chemical produced by certain brain cells. It 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.

In many patients, this reduces the symptoms of Parkinson's disease.

What are the ingredients in **SINEMET[®]?**

Medicinal ingredients: Levodopa and carbidopa

Non-medicinal ingredients: corn starch, magnesium stearate, microcrystalline cellulose,

pregelatinized starch.

SINEMET® 100 mg/25 mg tablets also contain D & C yellow No. 10 Lake.

SINEMET® 250 mg/25 mg tablets also contain FD&C Blue No. 2 Aluminum Lake.

SINEMET® comes in the following dosage forms:

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

Do not use SINEMET® if:

- you are allergic to any of its ingredients.
- you are taking certain monoamine oxidase (MAO) inhibitor medicines (such as those used for depression). You must stop using MAO inhibitor medicines at least two weeks before starting therapy with SINEMET®.
- you have untreated heart, liver, kidney, lung, blood or hormonal disease.
- you have narrow-angle glaucoma.
- you have been told that you should not take sympathomimetic medicines such as:
 - isoproterenol
 - amphetamines
 - epinephrine
- you have any suspicious skin lesions (moles) which have not been examined by your doctor or if you have ever had skin cancer.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SINEMET®. Talk about any health conditions or problems you may have, including if you:

- are taking or have taken levodopa in the past
- have a history of heart problems (heart attack and arrhythmias). Your doctor should carefully monitor you in an appropriate facility when you first start taking SINEMET®.
- have or have had ulcers in your gut (called "duodenal" or "peptic ulcer")
- have a history of convulsions/seizures
- have severe uncontrolled involuntary movements that can look like fidgeting, writhing or swaying called dyskinesia
- have any unusual conditions related to your eyes or eyesight (glaucoma)
- are going to have an operation that requires general anesthesia
- suffer from a medical condition called psychosis
- have or had skin cancer (melanoma)
- are pregnant, think you may be pregnant or become pregnant while taking SINEMET®. Your doctor will advise whether you should take SINEMET® while you are pregnant.
- are breastfeeding or wish to breastfeed. Your doctor will decide whether you should take SINEMET® while breastfeeding.
- have allergies
- have problems with your lungs

- have problems with your kidneys
- have problems with your liver
- have hormonal problems

Other warnings you should know about:

Laboratory tests and monitoring: When you take SINEMET® for a prolonged time, your doctor may:

- monitor your liver, kidney and heart function
- do blood tests

Physical activity: As you improve on SINEMET® you may increase your physical activity slowly depending if you have any other medical conditions.

Uncontrollable movements: SINEMET® may cause uncontrollable movements and “on and off” episodes. This may happen soon after you take SINEMET®.

Mental health changes/disturbances: SINEMET® may cause changes to your mental health.

- Tell you doctor **right away** if you start to feel depressed or have thoughts of suicide.
- Hallucinations (seeing or hearing things that are not there) can occur when taking SINEMET®.

Neuroleptic malignant syndrome: This is a disorder that causes you to have a high fever, confusion, altered states or consciousness and stiffness in your muscles. Neuroleptic malignant syndrome may happen if you suddenly:

- Reduce your dose
- Stop taking SINEMET®
- Switch medicines

Your doctor should monitor you when your dose is reduced or when you stop taking SINEMET®, especially if you take neuroleptics.

Driving and operating machinery: SINEMET® may cause you to feel sleepy or to fall asleep without warning. You should not drive or operate machinery until you know how SINEMET® affects you. If you ever feel sleepy or fall asleep without warning, do not drive or operate machinery, and tell your doctor **right away**.

Compulsive behaviours: While taking SINEMET®, you may have unusual urges and/or behaviours such as excessive:

- gambling
- sexual behaviour
- eating

- spending

You or your caregiver should tell your doctor if either of you notice that you have new or changes to your behaviour.

Skin: People with Parkinson's disease have a higher risk of developing skin cancer (melanoma). Your doctor should monitor you for skin cancer while you are taking SINEMET®. Tell your doctor if you have:

- suspicious, undiagnosed changed patches of pigmented skin
- irritated or irregular moles
- moles in which you have noticed changes

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SINEMET®:

- 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 MAO inhibitors)
- phenytoin (anti-epileptic medication)
- papaverine (medication for intestinal spasms)
- tetrabenazine (medication used to treat conditions related to involuntary movements such as Huntingtons Disease)
- isoniazid (medication to treat tuberculosis)
- anesthetics (drugs used during surgery)
- iron salts (such as multivitamins tablets)
- metoclopramide (for nausea and vomiting)
- Foods that are high in protein. This includes meat, fish, dairy products, seeds and nuts

How to take SINEMET®:

Usual dose:

Your doctor will tell you exactly how many tablets of SINEMET® you will need take each day and when you should take them.

SINEMET® tablets have a score-line on one side. Breaking the tablet in half may not give you half the dose.

DO NOT:

- stop taking SINEMET®, reduce the amount of SINEMET® you take or change your dose unless your doctor tells you to. If you suddenly stop or reduce your dose, you may experience the following symptoms: stiff muscles, fever and mental changes

- take any other antiparkinson medicines without first consulting your doctor. This includes other medicines containing levodopa and carbidopa
- give SINEMET® to other people
- use SINEMET® for any other condition

Tell your doctor **right away** if you notice any changes in your symptoms, such as nausea or abnormal movements. Your doctor may need to adjust your dose.

Overdose:

If you think you, or a person you are caring for, have taken too much SINEMET®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed a dose, take it as soon as you remember. If it is almost time to take your next dose, do not take the dose you have missed, and take your next dose as scheduled.

What are possible side effects from using SINEMET®?

These are not all the possible side effects you may have when taking SINEMET®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects include:

- Nausea
- Vomiting
- Slow movements
- Sleepiness
- Dizziness
- Mental changes
- Dream abnormalities
- Hair loss
- Dark-coloured saliva, urine and sweat
- Eating disorder (anorexia)
- Chest pain
- Feeling weak and tired
- High blood pressure
- Low blood pressure
- Stomach pain
- Dry mouth
- Changes in tastes
- Diarrhea
- Constipation

- Back and shoulder pain
- Muscle cramps
- Bladder infection
- Drooling
- Burning sensation of the tongue
- Hiccups
- Gas
- Heart burn
- Grinding or clenching of teeth
- Weight loss
- Weight gain
- Leg pain
- Blurred vision
- Double vision
- Spasms that move the eye(s) into a fixed position (oculogyric crisis)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Dyskinesia: severe uncontrolled movements		✓	
COMMON			
Hallucinations: seeing or hearing things that are not there		✓	
RARE			
Allergic reactions: hives, itching, rash, swelling of the face, lips, mouth, tongue or throat, trouble breathing and/or swallowing			✓
Compulsive Behaviour: inability to resist the impulse to perform an action that could be harmful, such as gambling too much, increased sexual urges, uncontrollable urge to eat or spend money, or repeating meaningless actions		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Convulsion: seizure, spasms, shaking or fits		✓	
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse		✓	
Excessive sleepiness or falling asleep without warning while doing normal activities		✓	
Feeling of lightheaded-ness as when standing quickly		✓	
Melanoma (skin cancer): Changed patches of pigmented skin, including irritated or irregular moles, or moles in which you have noticed changes		✓	
Neuroleptic Malignant Syndrome: pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness		✓	
Priapism: Long-lasting (greater than 4 hours in duration) and painful erection of the penis		✓	
Uneven (irregular) heartbeat, palpitations, chest pain and/or discomfort, pain in jaw,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
shoulders, arm and/or back, shortness of breath, sweating, nausea or light-headedness			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

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

Keep out of reach and sight of children.

Do not use outdated medicine.

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 Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.organon.ca, or by calling Organon Canada at 1-844-820-5468.

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