

# SINEMET<sup>®</sup> TABLET

Carbidopa/Levodopa (25/100mg, 25/250 mg)

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## What SINEMET is used for

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

## Why has my doctor prescribed SINEMET?

Your doctor 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.

## How SINEMET works

SINEMET tablets contain 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.

## Before you use SINEMET

### - *When you must not use it*

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 doctor or if you have ever had skin cancer
- are being treated for depression with certain MAO inhibitor drugs
- 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 apply to you, talk to your doctor or pharmacist before taking Sinemet.

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 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 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 doctor, who will help you weigh the benefits of the medication against possible hazards.

### - *Using 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 works.

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

- Medicines for Parkinson's

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- 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. Tell your doctor about all medicines you are taking or plan to take, including those obtained without prescription.

## How to use SINEMET

### - How much to use

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

### - When to use it

For best results take SINEMET every day. It is important to carefully follow your doctor's advice on how much SINEMET 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 are on a high protein diet, Sinemet may not work as well as it should.

### - 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 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

### - 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.
- Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

- Do not stop taking SINEMET 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 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?

Individual responses to medication may vary. Certain side effects that have been reported with SINEMET may affect some patients' ability to drive or operate machinery. (See "Side effects")

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.

## Side effects

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

- 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, discoloration of urine, sweat and/or saliva, diarrhea, increased sexual drive, fainting, palpitations (fast, strong, uneven heart beat), feeling of lightheadedness when standing quickly, dizziness, sleepiness, sudden sleep onset episodes, vomiting, loss of appetite, slow

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movement, compulsive gambling, and melanoma (skin cancer).

- 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](http://portal.bpfk.gov.my) (Consumers → Reporting)

## How can I learn more about SINEMET?

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

## Storage and Disposal of SINEMET

### - Storage

- SINEMET should be kept below 30°C. Keep in tightly closed container, protected from light and moisture.
- Keep SINEMET out of the reach of children.

### - Disposal

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.

## Product Description

### - *What it looks like*

**SINEMET TABLET 25/100 mg:**  
Yellow, round tablet with 650 on one side and plain on the other side.

**SINEMET TABLET 25/250 mg:**  
Light dapple blue, round tablet with 654 on one side and plain on the other side.

### - *Ingredients*

Active ingredients:  
SINEMET (carbidopa, levodopa) is a tablet. Each tablet contains carbidopa and levodopa as the active ingredients in the following strengths:

**SINEMET TABLET 25/100 mg:**  
Each tablet contains 25 mg of carbidopa and 100 mg of levodopa.

**SINEMET TABLET 25/250 mg:**  
Each tablet contains 25 mg of carbidopa and 250 mg of levodopa.

Inactive ingredients:  
hydroxypropyl cellulose, pregelatinized starch, crospovidone, microcrystalline cellulose, magnesium stearate, quinoline yellow aluminum lake (Sinemet 25/100 mg) and FD&C blue #2 aluminum lake (Sinemet 25/250 mg).

### - *MAL number(s)*

**SINEMET TABLET 25/100 mg:**  
MAL12085068ACRZ

**SINEMET TABLET 25/250 mg:**  
MAL12085069ACRZ

## Product Manufacturer

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

## 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.

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