

SINEMET®

25/250 & 25/100 mg tablets
Carbidopa/Levodopa

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What is Sinemet® and what it is used for

- Sinemet® contains two different medicines called: levodopa and carbidopa.
- Levodopa, an aromatic amino acid, turns into a material called 'dopamine' in your brain. The dopamine helps to improve the signs of your Parkinson's disease;
 - Carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.
- Sinemet® is indicated for the treatment of Parkinson's disease and syndrome.
- Sinemet® improves the symptoms of Parkinson's disease. Parkinson's disease is a long-term illness where:
- you become slow and unsteady.
 - your muscles feel stiff.
 - you may develop shaking or trembling (called 'tremor').

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

2. Before you take Sinemet®

Do not take Sinemet® if:

- you are allergic (hypersensitive) to levodopa or carbidopa or any of the other ingredients of Sinemet® (listed in Section 6).
- you are taking certain medicines called MAOIs

(Monoamine Oxidase Inhibitors) used for depression.

You need to stop using these medicines at least two weeks before you start Sinemet® (see also under 'Taking other medicines' below).

- you have a condition called 'narrow-angle glaucoma' that may cause a sudden build up of pressure in the eye.
- you have a severe mental disorder.
- you have a suspicious undiagnosed skin lesions or a history of melanoma.
- you are pregnant, might become pregnant, or are breast-feeding.

Do not take Sinemet® if any of the above applies to you.

If you are not sure, talk to your doctor or pharmacist before taking Sinemet®.

Take special care with Sinemet®

Check with your doctor or pharmacist before taking your medicine if:

- you have a history of fits (convulsions).
- you have had an ulcer in your gut (called 'duodenal' or 'peptic ulcer') or have vomited blood.
- you have had a heart attack, heart beat problems, circulation or breathing problems.
- you have had kidney, liver or hormonal problems.
- you have had depression or other mental problems.
- you have a condition called 'chronic wide-angle glaucoma' that may cause a build up of pressure in the eye.
- you will need to have regular checks on the pressure in your eye.
- you sometimes have sudden sleep attacks or sometimes feel very sleepy.
- you are due to have surgery.

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

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® works.

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

- Medicines for Parkinson's disease containing levodopa:
 - You will need to wait 12 hours after your last dose before starting Sinemet® (see section 3).
 - Tell the doctor or pharmacist even if you have only taken them in the past.
- Iron, ferrous sulfate or ferrous gluconate decrease the availability of carbidopa and/or levodopa.
- Medicines called monoamine oxidase inhibitors.
- Dopamine D2 receptor antagonists (e.g., phenothiazines, butyrophenones and risperidone) and isoniazid

may reduce the therapeutic effects of levodopa.

- Phenytoin which is used to treat fits (convulsions) and papaverine which is used to treat impotence in men have been reported to reverse the beneficial action of levodopa.
 - Antihypertensive agents: Symptomatic postural hypotension has occurred when Sinemet® is added to the treatment of patients receiving some antihypertensive drugs. Therefore, when therapy with Sinemet® is started, dosage adjustment of the antihypertensive drug may be required.
- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine. Your doctor or pharmacist has a more complete list of medicines to avoid while taking Sinemet®.

Taking Sinemet® with food and drink

Try to avoid taking your tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese), Sinemet® may not work as well as it should.

Pregnancy and breast-feeding

Do not take Sinemet® if you are pregnant, might become pregnant or are breast-feeding. Levodopa, one of the substances in Sinemet®, is passed into human milk. Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines

Levodopa may be associated with somnolence and very rarely episodes of sudden onset of sleep. In some cases, these episodes may occur without awareness or warning during daily activities. Patients must be cautious while driving or operating machines while being treated with levodopa, or other dopaminergic agents. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines.

3. How to take Sinemet®

Always take Sinemet® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage should be titrated to individual needs and this may require adjusting both the dose and the frequency of administration.

Sinemet® tablets are available in a 1:4 ratio of carbidopa to levodopa (Sinemet® 25/100 mg) as well as a 1:10 ratio (Sinemet® 25/250 mg).

Tablets of the two ratios may be given separately or combined as needed to provide the optimum dosage. (Each tablet of Sinemet® is designed to divide in half with minimal pressure).

The usual initial dose is one tablet of Sinemet® 25/100 three times a day. This dosage schedule provides 75 mg

of carbidopa per day. Dosage may be increased by one tablet every day or every other day, as necessary, until a dosage of eight tablets of Sinemet® 25/100 a day is reached.

For patients starting with Sinemet® 25/250, the initial dose is one-half tablet taken once or twice daily. However, this may not provide the optimal amount of carbidopa needed by many patients. If necessary, add 1/2 tablet every day or every other day until optimal response is reached.

Response has been observed in one day, and sometimes after one dose. Fully effective doses usually are reached within seven days as compared to weeks or months with levodopa alone.

Taking this medicine

- Take this medicine by mouth. You must swallow your tablets whole. Do not crush or chew the tablets.
- Although your medicine can have an effect after one day, it may take up to seven days to work.
- Take them at regular time intervals according to your doctor's instructions.
- Do not change the times at which you take your tablets or take any other medicines for Parkinson's disease without first consulting your doctor. You should not take Sinemet® tablets at intervals of less than 4 hours apart.
- Try to avoid taking your tablets with a heavy meal.
- In case of an accidental overdose, call your doctor right away or go to the nearest emergency room.

If you have had levodopa before

Your doctor will ask you to stop taking your medicine for Parkinson's disease for 12 hours before you start taking Sinemet®.

A daily dosage of Sinemet® should be chosen that will provide approximately 25% of the previous levodopa dosage. Patients who are taking less than 1500 mg of levodopa a day should be started on one tablet of Sinemet® 25/100 mg three or four times a day. The suggested starting dosage for most patients taking more than 1500 mg of levodopa is one tablet of Sinemet® 25/250 mg three or four times a day.

Pediatric use

Safety and effectiveness in pediatric patients have not been established. Use of the drug in patients below the age of 18 is not re-commended.

If you take more Sinemet® than you should

If you take too many tablets see your doctor immediately.

If you forget to take Sinemet®

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

If you stop taking Sinemet®

Do not stop taking Sinemet® or change your dose without talking to your doctor first. When you stop taking Sinemet® the follow-up can occur: stiff muscles, high temperature (fever) and mental changes. If you have any further questions on the use of this product, ask your doctor or pharmacist for more information.

4. Possible side effects

Like all medicines, Sinemet® can cause side effects, although not everybody gets them.

Stop taking Sinemet® and see your doctor straight away, if you notice any of the following side effects:

The most common side effects reported with Sinemet® have included dyskinesias, such as choreiform, dystonic, and other involuntary movements, and nausea. The following side effects have been reported with Sinemet®:

- Body as a whole: chest pain, asthenia
- Cardiovascular: cardiac irregularities, hypotension, or orthostatic effects including orthostatic hypotension, hypertension, syncope, phlebitis, palpitation
- Gastrointestinal: dark saliva, gastrointestinal bleeding, development of duodenal ulcer, anorexia, vomiting, diarrhea, constipation, dyspepsia, dry mouth, taste alterations
- Hematologic: agranulocytosis, hemolytic and non-hemolytic anemia, thrombocytopenia, leukopenia
- Hypersensitivity: angioedema, urticaria, pruritus, Henoch-Schonlein purpura, bullous lesions (including pemphigus-like reactions)
- Musculoskeletal: back pain, shoulder pain, muscle cramps
- Nervous system/psychiatric: psychotic episodes including delusions, hallucinations, and paranoid ideation, neuroleptic malignant syndrome, bradykinetic episodes ('on-off' phenomenon), confusion, agitation, dizziness, somnolence, dream abnormalities including nightmares, insomnia, paresthesia, headache, depression with or without development of suicidal tendencies, dementia, pathological gambling, increased libido including hypersexuality, impulse control symptoms. Convulsions also have occurred; however, a causal relationship with Sinemet® has not been established.
- Respiratory: dyspnea, upper respiratory infection
- Skin: rash, increased sweating, alopecia, dark sweat
- Urogenital: urinary tract infection, urinary frequency, dark urine
- Laboratory tests: decreased hemoglobin and hematocrit; abnormalities in alkaline phosphatase, SGOT (AST), SGPT (ALT), lactic dehydrogenase, bilirubin, blood urea nitrogen (BUN), creatinine, uric acid, positive Coombs test, elevated serum glucose, white blood cells, bacteria, and blood in the urine.

Other side effects that have been reported with levodopa alone and with various carbidopa-levodopa formulations, and may occur with Sinemet® are:

- Body as a whole: abdominal pain and distress, fatigue
 - Cardiovascular: myocardial infarction
 - Gastrointestinal: gastrointestinal pain, dysphagia, sialorrhea, flatulence, bruxism, burning sensation of the tongue, heartburn, hiccups
 - Metabolic: edema, weight gain, weight loss
 - Musculoskeletal: leg pain
 - Nervous system/psychiatric: ataxia, extrapyramidal disorder, falling, anxiety, gait abnormalities, nervousness, decreased mental acuity, memory impairment, disorientation, euphoria, blepharospasm (which may be taken as an early sign of excess dosage; consideration of dosage reduction may be made at this time), trismus, increased tremor, numbness, muscle twitching, activation of latent Horner's syndrome, peripheral neuropathy
 - Respiratory: pharyngeal pain, cough
 - Skin: malignant melanoma, flushing
 - Special Senses: oculogyric crises, diplopia, blurred vision, dilated pupils
 - Urogenital: urinary retention, urinary incontinence, priapism
 - Miscellaneous: bizarre breathing patterns, faintness, hoarseness, malaise, hot flashes, sense of stimulation
 - Laboratory tests: decreased white blood cell count and serum potassium, increased serum creatinine and uric acid, protein and glucose in urine.
- If any symptoms persist or you experience any other side effects not listed in the leaflet please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

5. How to store Sinemet®

- Keep out of reach and sight of children.
- Do not store above 30°C. Protect from light and moisture.
- Store in the original package.
- Do not use Sinemet® after the expiry date stated on the blister and carton. The expiry date refers to the last day of that month.
- 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.

6. Further information

What Sinemet® tablets contain

- The active substances in Sinemet® 25/250 mg are 25 mg of carbidopa (in anhydrous form) and 250 mg of levodopa.
- The active substances in Sinemet® 25/100 mg are 25 mg of carbidopa (in anhydrous form) and 100 mg of

levodopa.

- Inactive ingredients are: pregelatinized starch, corn starch, microcrystalline cellulose and magnesium stearate. Sinemet® 25/250 mg tablets also contain FD&C Blue #2 (Indigo Carmine). Sinemet® 25/100 mg tablets also contain D&C Yellow #10 Aluminum Lake.

What Sinemet® tablets look like and contents of the pack

- Sinemet® 25/250 mg are light dapple-blue, biconvex, oval-shaped tablets, one side with a deep angle breakline, the other side engraved "ALG S275".
- Sinemet® 25/100 mg are yellow, biconvex, oval-shaped tablets, one side with a deep angle breakline, the other side engraved "ALG S125".
- Sinemet® 25/250 mg is available in blister packs of 20 tablets.
- Sinemet® 25/100 mg is available in blister packs of 100 tablets.

Not all strengths may be marketed.

For more information about this medicinal product, please contact:

Algorithm SAL
Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries
Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@blgxn.net
Website : www.algorithm-lb.com

Also contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

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