

SINDOPA *(Levodopa/Carbidopa)*



What is in this leaflet

This leaflet answers some common questions about Sindopa. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have benefits and risks. Your doctor has weighed the risks of you taking SINDOPA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What SINDOPA is used for

SINDOPA is used to treat some of the symptoms of Parkinson's disease. This is a disease of the nervous system that mainly affects body movement. The three main symptoms are shaking (tremor), muscle stiffness and slow, unsteady movement.

SINDOPA is most helpful in improving slow movement and muscle stiffness. It can also be helpful in treating shaking, difficulty in swallowing, drooling and unstable posture.

Parkinson's disease is caused by the brain not making enough of a chemical called dopamine. Dopamine helps the brain to control muscle movement.

SINDOPA contains two active ingredients, levodopa and carbidopa. Levodopa is a chemical closely related to dopamine, which allows the body to make its own dopamine. Carbidopa makes sure that enough levodopa gets to the brain where it is needed. In many patients, SINDOPA reduces some of the symptoms of Parkinson's disease.

SINDOPA is not recommended for use in children under the age of 18, as its safety and effectiveness have not been established in this age group.

Ask your doctor if you have any questions about why SINDOPA has been prescribed for you. Your doctor may have prescribed SINDOPA for another reason.

SINDOPA is available only with a doctor's prescription.

Before you take SINDOPA

When you must not take it

Do not take SINDOPA if:

- you are allergic to medicines containing levodopa, carbidopa or any of the ingredients listed at the end of this leaflet.
- you have any unusual skin lumps or moles which have not been checked by your doctor, or if you have ever had skin cancer or melanoma.
- you have a type of glaucoma called narrow-angle glaucoma.
- you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI), or you have previously taken a MAOI within the last 14 days. Some examples of MAOIs are phenelzine (Nardil) and tranylcypromine (Parnate).

- **you are breastfeeding.** It is not known if SINDOPA passes into breast milk. However, because many medicines pass into breast milk and may harm the baby, SINDOPA should not be used during breastfeeding.
- **if the expiry date (EXP.) printed on the pack has passed.** Do not take SINDOPA if the packaging shows signs of tampering or the tablets do not look quite right.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

- you are allergic to any other medicines, foods, dyes or preservatives.
- you are pregnant or plan to become pregnant.
Your doctor will discuss the risks and benefits of taking SINDOPA during pregnancy.
- you wish to breastfeed.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- depression, mental illness or psychiatric problems
- uncontrollable twitching or jerking movements of the body
- heart conditions, including irregular heart beat (arrhythmia)
- lung conditions, including asthma
- kidney or liver problems
- hormonal problems
- convulsions or fits
- glaucoma
- stomach ulcer and/or duodenal ulcers (peptic ulcer)
- high blood pressure.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you are currently taking levodopa or have taken it in the past. Some examples of medicines which contain levodopa are Madopar and Sinemet.

If you have not told your doctor about any of the above, tell them before you start taking SINDOPA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by SINDOPA, or may affect how well it works. These include:

- selegiline (Eldepryl, Selgene), another medicine used to treat Parkinson's disease
- medicines used to treat high blood pressure
- some medicines used to treat depression
- some medicines used to treat mental illness or psychiatric problems
- iron preparations (e.g. ferrous sulphate or ferrous gluconate)
- phenytoin (Dilantin), a medicine used to treat convulsions
- isoniazid, a medicine used to treat tuberculosis.
- Some medications used in minor surgery such as papaverine.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking SINDOPA.

How to take SINDOPA

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose varies from patient to patient.

The usual starting dose is one SINDOPA tablet three times a day. Your doctor may increase this dose depending on how you respond to this medicine whether or not you are taking any other medicines.

How to take SINDOPA

Swallow the tablets with a glass of water.

SINDOPA tablets can be divided in half along the breakline, if your doctor has prescribed half a tablet.

When to take SINDOPA

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take SINDOPA for

Keep taking SINDOPA for as long as your doctor recommends.

SINDOPA helps control some of the symptoms of Parkinson's disease, but does not cure your condition. It is important that you take SINDOPA every day on a regular basis.

If you forget to take SINDOPA

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

While you are taking SINDOPA

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking SINDOPA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking SINDOPA.

If you become pregnant while taking SINDOPA, tell your doctor as soon as possible.

If you plan to have surgery, including dental surgery, that needs a general anaesthetic, tell your doctor or dentist that you are taking SINDOPA.

If you are diabetic, check with your doctor or pharmacist before using urine sugar tests. SINDOPA may cause false test results with some urine sugar tests.

If you need to have any other blood or urine tests, tell your doctor that you are taking SINDOPA. SINDOPA may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

You may need to have tests to check your blood, liver, kidneys and heart. Your doctor may also want to exam your skin to check for any abnormal moles or skin lesions.

Tell your doctor if you feel SINDOPA is not working as well as it did previously.

In some people who have been taking SINDOPA for a long time, such as a year or more, sudden and unexpected losses of movement may occur. These may last from a few minutes to several hours. Afterwards, the person can move as before. This is called the on-off effect. If this happens, your doctor may want adjust your medicine.

Things you must not do

Do not stop taking SINDOPA, or lower the dose, without checking with your doctor.

Stopping SINDOPA suddenly may cause muscle stiffness, fever and mental changes. Your doctor may want you to gradually reduce the amount of SINDOPA you are taking before stopping completely.

Do not use SINDOPA to treat any other conditions unless your doctor tells you to.

Do not give SINDOPA to anyone else, even if they have the same condition as you.

Things to be careful of

Do not drive or operate machinery until you know how SINDOPA affects you.

SINDOPA may cause dizziness, lightheadedness, sudden sleep onset episodes, or excessive drowsiness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. This is because your blood pressure is suddenly falling. Getting up slowly may help. If this problem continues or gets worse, tell your doctor.

Be careful not to eat a diet high in protein.

The amount of levodopa absorbed by your body may be reduced if your diet is high in protein. Ask your doctor, pharmacist or dietician to check your diet.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SINDOPA.

SINDOPA helps most people with Parkinson's disease, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- abnormal uncontrolled movements including muscle twitching or spasms, which may or may not be like your Parkinson's symptoms
- dizziness, lightheadedness when getting up quickly, fainting
- nausea (feeling sick), vomiting, loss of appetite
- sudden episodes of sleep onset, excessive drowsiness
slow movements
- twitching or spasm of the eyelids
- unusual behaviour or urges, including an unusual urge to gamble or increased sexual desire and/or behaviours.

The side effects listed above are usually mild.

It is important to tell your doctor as soon as possible if you notice any of the following:

- difficulty or pain in passing urine, blood in the urine
- changes in mood such as depression
- forgetfulness
- signs of anaemia such as tiredness, being short of breath and looking pale
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal
- numbness or tingling in the hands or feet.
- alopecia, dark sweat.
- any change to a mole/moles on your skin, including any change to the size, shape, colour or feel of a mole.

The above list includes the more serious side effects of SINDOPA. If you experience any of them, you may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- skin rash, itching or hives
- swelling of the face, lips or tongue, difficulty in swallowing
- difficulty breathing, wheezing or shortness of breath

- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- vomiting blood or material that looks like coffee grounds
- chest pain
- fast or irregular heart beats, also called palpitations
- muscle stiffness accompanied by fever
- mental changes such as feeling very fearful or paranoid, hallucinations.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

In case of overdose

You should only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any SINDOPA by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of SINDOPA with you if you can.

Keep telephone numbers for these places handy.

After taking SINDOPA

Storage

Keep SINDOPA where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack, they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store SINDOPA or any other medicine in the bathroom or near a sink.

Do not leave SINDOPA in the car or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking SINDOPA, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What Sindopa looks like

SINDOPA is a round, yellow, scored tablet marked 'LC' breakline '2' on one side and 'α' on the other side.

Ingredients

The active ingredients in SINDOPA are levodopa and carbidopa. Each SINDOPA tablet contains 100 mg of levodopa and 25 mg of carbidopa.

The tablets also contain the following inactive ingredients:

- maize starch
- povidone
- microcrystalline cellulose
- magnesium stearate
- purified talc
- sodium starch glycollate
- quinoline yellow.

The tablets are gluten and lactose free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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