

KINSON

levodopa and carbidopa (as monohydrate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about KINSON.

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 KINSON against the benefits expected 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 KINSON is used for

KINSON 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 and unsteady movement.

People with ParKINSON's disease often walk with a shuffle as they have difficulty in initiating movement. If untreated, ParKINSON's disease can cause difficulty in performing normal daily activities.

KINSON 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.

The symptoms of ParKINSON's disease are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. Dopamine sends messages in the part of the brain that controls muscle movement.

When too little dopamine is produced, slowness of movement results.

KINSON 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, KINSON reduces some of the symptoms of ParKINSON's disease.

Your doctor may have prescribed KINSON for another reason.

Ask your doctor if you have any questions about why KINSON has been prescribed for you.

KINSON is available only with a doctor's prescription.

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Before you take KINSON

When you must not take it

Do not take KINSON if you are allergic to medicines containing levodopa, carbidopa or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

Do not take KINSON if you have:

- any unusual skin lumps or moles which have not been checked by your doctor
- a history of melanoma (a type of skin cancer).

Do not take KINSON if you have a type of glaucoma called narrow-angle glaucoma.

Do not take KINSON if 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).

Do not take KINSON if you are breastfeeding or plan to breastfeed.

It has been shown that one of the active ingredients of KINSON passes into breast milk. Therefore, because of the potential harm to the baby, KINSON should not be used during breastfeeding.

Do not give KINSON to a child or teenager below 18 years old, unless advised by the child's doctor.

The safety and effectiveness of KINSON in children and teenagers under 18 years old has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking KINSON during pregnancy.

Tell your doctor if 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
- heart disease, including irregular heart beat (arrhythmia)
- lung disease, including asthma
- kidney, liver or hormonal problems
- convulsions or fits
- glaucoma
- peptic ulcer disease

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

Tell your doctor if you or your family member/caregiver notices you are developing urges to gamble, excessive eating or spending, medicine use or repetitive purposeless activities with other medicines for ParKINSON's Disease, and/or other intense urges that could harm yourself or others. These behaviours are called impulse control disorders. Your doctor may need to review your treatments.

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 KINSON.

Taking other medicines

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

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

- selegiline (Eldepryl, Selgene), another medicine used to treat ParKINSON's disease
- some medicines used to treat high blood pressure
- some medicines used to treat depression
- some medicines used to treat mental illness or psychiatric problems
- some medicines used to treat diseases related to involuntary movements.
- phenytoin (Dilantin), a medicine used to treat convulsions
- isoniazid, a medicine used to treat tuberculosis.
- iron supplements and multivitamins containing iron

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 KINSON.

How to take KINSON

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

Your doctor will tell you how many tablets to take each day. The dose varies considerably from patient to patient.

The usual starting dose is one KINSON 100/25mg tablet three times a day. Your doctor may adjust this dose depending on how you respond to this medicine whether or not you are taking any other medicines.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

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 it for

Keep taking KINSON for as long as your doctor recommends.

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

Continue taking KINSON for as long as your doctor prescribed.

Do not stop taking KINSON, or lower the dosage, without checking with your doctor.

Your doctor may want you to gradually reduce the amount of KINSON you are using before stopping completely. This may help

reduce the possibility of withdrawal symptoms such as muscle stiffness, fever or mental changes.

If you forget to take it

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.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much KINSON. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking KINSON

Things you must do

If you feel light-headed, dizzy or faint get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy while taking KINSON. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem

continues or gets worse, tell your doctor.

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

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

If you become pregnant while taking KINSON, tell your doctor.

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

If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.

KINSON 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 KINSON.

KINSON 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 make sure that KINSON is not affecting your blood, liver, kidneys and heart.

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

In some people who have been taking KINSON for long periods of 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 may unexpectedly occur again and again. This is called the "on-off" effect. If this happens, your doctor may want to adjust your medicine.

Things you must not do

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

Stopping KINSON suddenly may cause muscle stiffness, fever and mental changes. Your doctor may

want you to gradually reduce the amount of KINSON you are taking before stopping completely.

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

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

Things to be careful of

Be careful when driving or operating machinery until you know how KINSON affects you.

KINSON may cause dizziness or lightheadedness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded. Drinking alcohol can make dizziness and lightheadedness worse.

In addition, in very rare cases, KINSON may cause excessive sleepiness and sudden onset of sleep.

If you experience these effects, do not drive or operate machinery until these effects are resolved.

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 KINSON.

KINSON 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
- nausea (feeling sick), vomiting, loss of appetite
- discolouration of urine, sweat and/or saliva
- dark saliva
- sudden episodes of sleep onset, excessive drowsiness
- slow movements
- dream abnormalities, sleepiness or sudden onset of sleep
- twitching or spasm of the eyelids
- hair loss
- diarrhoea

Tell your doctor if you experience any of these behaviours:

You may experience an inability to resist the impulse to perform an action that could be harmful, which may include:

- strong impulses to gamble
- increased sexual drive
- uncontrollable excessive shopping
- spending, binge/compulsive eating

- taking medicines and repetitive purposeless activities
- and/or other urges

These are possible side effects of KINSON. For the most part, the above side effects have been mild.

Tell your doctor immediately if you notice any of the following:

- blood in the urine
- difficulty or pain in passing urine
- skin rash, itching
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- changes in mood such as depression
- forgetfulness
- signs of anaemia such as tiredness, headaches, being short of breath, dizziness and looking pale
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nose bleeds
- numbness or tingling in the hands or feet
- fainting
- signs of melanoma, such as new skin spots or changes to the size, shape, colour or edges of an existing skin spot, freckle or mole.

The above list includes serious side effects which 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:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- 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 heartbeats, 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.

Contact your doctor as soon as possible if you or someone you know is showing signs of unusual behaviour while taking KINSON.

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.

After taking KINSON

Storage

Keep KINSON 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 bottle until it is time to take them.

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

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

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

Do not leave KINSON in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

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Product description

What it looks like

KINSON is a 9mm flat bevelled-edged yellow tablet debossed LC/2 on one side and 'alpha' on the reverse.

Each bottle contains 100 tablets.

Ingredients

The active ingredients in KINSON are levodopa and carbidopa (as monohydrate). Each KINSON 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

KINSON contains sulfites.

Manufacturer

KINSON is made in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

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