Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using KINSON?

KINSON contains the active ingredients levodopa and carbidopa. KINSON is used to treat some of the symptoms of Parkinson's disease.

For more information, see Section <u>1. Why am I using KINSON?</u> in the full CMI.

2. What should I know before I use KINSON?

Do not use if you have ever had an allergic reaction to KINSON or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use KINSON? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KINSON and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use KINSON?

- Your doctor will tell you how many tablets to take each day. Follow all directions given to you by your doctor carefully.
- Swallow the KINSON tablet whole or as half tablets, with a glass of water.

More instructions can be found in Section 4. How do I use KINSON? in the full CMI.

5. What should I know while using KINSON?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using KINSON.
- If you notice times where KINSON does not appear to be working as

	 well as it did previously, tell your doctor. If you notice any changes in your own health, or 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 as soon as possible.
Things you should not do	 Do not stop taking KINSON, or lower the dosage, without checking with your doctor. Do not give KINSON to anyone else, even if they have the same condition as you.
Driving or using machines	 Be careful when driving or operating machinery until you know how KINSON affects you. KINSON may cause dizziness or lightheadedness in some people.
Drinking alcohol	 If you drink alcohol, dizziness or light-

	headedness may be worse.
Looking after your medicine	 Keep your tablets in the bottle until it is time to take them.
	 Store in a cool, dry place where the temperature stays below 30°C. Keep it where children cannot reach it.

For more information, see Section <u>5. What should I know while using KINSON?</u> in the full CMI.

6. Are there any side effects?

The most common side effects are nausea, hallucinations, confusion, dizziness, abnormal uncontrolled movements and dry mouth. Serious side effects include blood in the urine, difficult or painful urination, changes in mood, forgetfulness, signs of anaemia such as tiredness and shortness of breath, frequent or worrying infections, bruising or bleeding, fainting, skin changes, numbness or tingling in the feet.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Active ingredient(s): levodopa and carbidopa

Consumer Medicine Information (CMI)

This leaflet provides important information about using KINSON. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KINSON.

Where to find information in this leaflet:

- 1. Why am I using KINSON?
- 2. What should I know before I use KINSON?
- 3. What if I am taking other medicines?
- 4. How do I use KINSON?
- 5. What should I know while using KINSON?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using KINSON?

KINSON contains the active ingredients levodopa and carbidopa.

KINSON is used to 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.

2. What should I know before I use KINSON?

Warnings

Do not use KINSON if:

- you are allergic to levodopa or 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.
 - o skin rash, itching or hives.
 - Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing.
- always check the ingredients to make sure you can use this medicine.
- you have any unusual skin lumps or moles which have not been examined by your doctor, or if you have ever had skin cancer or melanoma.
- you have a type of glaucoma called narrow-angle glaucoma.
- are being treated for depression with certain medicines called monoamine oxidase inhibitors (MAOI), or if you have previously taken a MAOI within the last 14 days.
- Some examples of MAOIs are phenelzine (Nardil) and tranylcypromine (Parnate).

- Ask your doctor or pharmacist if you are not sure whether you are taking one of these medicines.
- 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.
- the packaging is torn or shows signs of tampering or the expiry date on the pack has passed.
- If you take this medicine after the expiry date has passed, it may not work. If it has expired or is damaged, return it to your pharmacist for disposal.
- If you are not sure whether you should start taking KINSON, talk to your doctor.
- Do not give KINSON to a child or teenager below the age of 18, unless advised by the child's doctor.
- The safety and effectiveness of KINSON in children and
- teenagers under 18 years of age has not been established.

Check with your doctor if:

- you are pregnant or intend to become pregnant.
- Your doctor will discuss the possible risks and benefits of using KINSON during pregnancy.
- you have or have had any medical conditions, especially the following:
 - o depression, mental illness or psychiatric problems
 - heart disease, including irregular heartbeat (arrhythmia).

- o lung disease, including asthma.
- o kidney, liver or hormonal problems
- convulsions or fits
- o glaucoma
- o peptic ulcer disease
- you or your family member/caregiver notices you are developing urges to gamble, increased sexual urges, 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.
- you have previously been or are currently being treated with levodopa.
- Some examples of medicines which contain levodopa are Madopar and Sinemet.
- you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
- If you have not told your doctor about any of the above,
- tell them before you take any KINSON.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with KINSON and affect how it works. These include:

- some medicines used to treat high blood pressure or heart disease.
- 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.
- some medicines use to treat muscle spasms.

- Phenytoin (Dilantin), a medicine used to treat convulsions.
- isoniazid, a medicine used to treat tuberculosis.
- selegiline (Eldepryl, Selgene), another medicine used to treat Parkinson's disease.
- iron supplements and multivitamins containing iron.

These medicines may be affected by KINSON or may affect how well the tablets work. You may need different amounts of your medicine, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KINSON.

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

4. How do I use KINSON?

How much to take

- Take KINSON only when prescribed by your doctor.
- Your doctor will tell you how many tablets to take each day. This depends on the severity of your condition, your response to treatment and whether you are taking other medicines. The dose varies considerably from patient to patient.

- The usual starting dose is one 100/25 mg tablet taken three times a day. Your doctor will adjust this dose depending on the severity of your condition, your response to treatment and whether you are taking other medicines.
- Follow all directions given to you by your doctor carefully.
- They may differ from the information contained in this leaflet.
- If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take KINSON

 Swallow KINSON tablets whole, with a glass of water.

When to take KINSON

- 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 KINSON

 Keep taking KINSON for as long as your doctor recommends.

KINSON helps control some of your symptoms of Parkinson's disease but does not cure it. Therefore, KINSON must be taken every day. Continue taking KINSON for as long as your doctor prescribes.

 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 and mental changes.

If you forget to use KINSON

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 tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you use too much KINSON

If you think that you have used too much KINSON, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

 go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using KINSON?

Things you should do

- If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.
 - Although rare, 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 the 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.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking KINSON.
- Tell all the doctors, dentists and pharmacists who are treating you that you are taking KINSON.
- If you experience times where KINSON does not appear to be working as well as it did previously, tell your doctor.

After taking this medicine for long periods of time, such as a year or more, some people suddenly lose the ability to move. This loss of movement may last from a

few minutes to several hours. The person is then able to move as before. This condition may unexpectedly occur again and again. This is called the "on-off" effect. Your doctor may prescribe you a stronger dose of KINSON or may ask you to take it more frequently. Your doctor may need to prescribe you a different medicine.

- Have blood tests when your doctor says to make sure KINSON is not causing any problems with your blood, liver, kidneys or heart.
- 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 become pregnant while taking KINSON, tell your doctor.
- Be careful not to eat a diet high in protein.
 The amount of levodopa absorbed by the body may be impaired if you eat a diet high in protein. Ask your doctor, pharmacist or dietician to check your diet.
- 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.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how KINSON affects you.

KINSON may cause dizziness or light-headedness in some people. Make sure you know how you react to KINSON before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

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 have resolved.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- Keep your tablets in the bottle until it is time to take them.
- If you take the tablets out of the bottle, they may not keep well.
- Store KINSON below 30°C in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.
- Heat and dampness can damage some medicines.
- 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.

When to discard your medicine

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

Do not use this medicine after the expiry date.

6. Are there any 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 a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 abnormal uncontrolled movements, which may or may not resemble your Parkinson's symptoms 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 feeling sick (nausea), vomiting, loss of appetite dizziness, light-headedness when standing quickly dry mouth discolouration of urine, sweat and/ or saliva 	

Less serious side effects	What to do
 urinary tract infection which often presents as a strong urge to urinate accompanied by pain or burning during urination dream abnormalities sleepiness or sudden onset of sleep slow movements twitching or spasm of the eyelids hair loss diarrhoea 	
 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 or spending binge/compulsive eating 	Tell your doctor if you experience any of these behaviours

Less serious side effects	What to do
 taking medicines and repetitive purposeless activities and/or other urges 	

Serious side effects

Serious side effects	What to do
 blood in the urine difficult or painful urination 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 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
 fainting skin rash, itchiness pinkish, itchy swellings on the skin, also called hives or nettle rash numbness or tingling in the hands or feet 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. swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing 	
 bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea vomiting blood or material that looks like coffee grounds chest pain 	

Serious side effects	What to do
 fast or irregular heartbeats, also called palpitations 	
 muscle stiffness accompanied by fever 	
 mental changes such as feeling very fearful or paranoid, hallucinations 	
 shortness of breath, difficulty breathing or wheezing 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KINSON contains

Active ingredient (main ingredient)	levodopa 100 mgcarbidopa 25 mg
Other ingredients (inactive ingredients)	 maize starch povidone microcrystalline cellulose magnesium stearate purified talc sodium starch glycollate quinoline yellow aluminium lake
Potential allergens	sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What KINSON looks like

KINSON is a 9mm flat bevelled-edged yellow tablet debossed LC/2 on one side and 'alpha' on the reverse (AUST R 49481).

Each bottle contains 100 tablets.

Who distributes KINSON

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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