PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

RAZAGIN™ (1 mg) tablets

Rasagiline

Sugar free

Read all of this leaflet carefully before you start taking RAZAGIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RAZAGIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RAZAGIN is and what it is used for
2. What you need to know before you take RAZAGIN
3. How to take RAZAGIN
4. Possible side effects
5. How to store RAZAGIN
6. Contents of the pack and other information

1. What RAZAGIN is and what it is used for

RAZAGIN contains the active substance rasagiline, which is used for the treatment of Parkinson's disease in adults. It belongs to a group of medicines called monoamine oxidase (MAO)-B inhibitors.

With Parkinson's disease, there is a loss of cells that produce dopamine in the brain. Dopamine is a chemical in the brain, involved in movement control. RAZAGIN helps to increase and sustain levels of dopamine in the brain.

RAZAGIN can be used together with, or without, levodopa (another medicine that is used to treat Parkinson's disease).

2. What you need to know before you take RAZAGIN

Do not take RAZAGIN

- if you are hypersensitive (allergic) to rasagiline or any of the other ingredients of RAZAGIN (listed in section 6);
- if you have severe liver problems;
- if you are already taking monoamine oxidase (MAO) inhibitors (e.g. for treatment of depression or Parkinson's disease, or used for any other indication), including products obtained without prescription such as St. John's Wort, or pethidine (a strong pain killer). You must wait at least 14 days after stopping RAZAGIN treatment before starting treatment with MAO inhibitors or pethidine.

Warnings and precautions

Take special care with RAZAGIN:

- if you have liver problems.

You should speak to your doctor about any suspicious skin changes (see section 4).

RAZAGIN may cause drowsiness and may cause you to suddenly fall asleep during daytime activities, especially if you are taking other dopaminergic medicines (used for the treatment of Parkinson's disease). For further information please refer to section "Driving and using machines".

Tell your doctor if you or your family/carer notices that you are developing unusual behaviour where you cannot resist the impulse, urges or cravings to carry out certain harmful or damaging activities to yourself or others. These are called impulse control disorders. In patients taking RAZAGIN and/or other medicines used to treat Parkinson's disease, behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive spending, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts or feelings have been reported. Your doctor may need to adjust or stop your dose (see section 4).

Children

It is not known whether RAZAGIN is safe or effective in children. Therefore, RAZAGIN is not recommended for use under the age of 18.

Other medicines and RAZAGIN

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Do not take the following medicines while taking RAZAGIN:

These medicines will strengthen the effect of RAZAGIN and are very harmful to you if taken together:

- Monoamine oxidase (MAO) inhibitors (e.g. for treatment of depression; some examples are isocarboxazid, phenelzine, selegiline)
- St. John's Wort (a herbal remedy used for depression)
- Pethidine (a strong painkiller)

You must wait at least 14 days after stopping RAZAGIN treatment before starting treatment with MAO inhibitors or pethidine.

Especially tell your doctor if you are taking any of the following medicines.

These medicines will strengthen the effect of RAZAGIN and may be harmful to you if taken together:

- Certain antidepressants (selective serotonin reuptake inhibitors (SSRIs) such as citalopram, selective serotonin-norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, tricyclic antidepressants such as amitriptyline, or tetracyclic antidepressants such as mirtazapine).

  The use of RAZAGIN together with the antidepressants containing fluoxetine or fluvoxamine should be avoided.

  You should wait at least 5 weeks after stopping fluoxetine treatment before you start treatment with RAZAGIN.

  You should wait at least 14 days after stopping RAZAGIN treatment before you start treatment with fluoxetine or fluvoxamine.
- Sympathomimetics, such as those present in eye drops, nasal and oral decongestants and cold medicine containing ephedrine or pseudoephedrine.
- Dextromethorphan (a cough suppressant).
- Ciprofloxacin (an antibiotic, used against infections).

Taking/using the following with RAZAGIN may shorten/decrease the effect of RAZAGIN:

- Entacapone (for Parkinson's disease).
- Tell your doctor or pharmacist if you are smoking or intend to stop smoking. Smoking could decrease the amount of RAZAGIN in the blood.

RAZAGIN with food, drink and alcohol

You can take RAZAGIN before, during or after a meal with water.

Alcohol may enhance side effects such as dizziness and sleepiness.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking RAZAGIN.

You should not take RAZAGIN if you are pregnant.

If you become pregnant during treatment, contact your doctor immediately.

Do not take RAZAGIN if you are breastfeeding.

No human data on the effect of RAZAGIN on fertility are available.

Driving and using machines

RAZAGIN may cause sleepiness or sudden sleep episodes, which may have a major influence on your ability to drive and use machines.

These side effects may be further strengthened if you take other medicines to treat the symptoms of your Parkinson's disease, or if you take medicines which can make you feel drowsy, or if you take alcohol (see "RAZAGIN with food, drink and alcohol").

You should not drive or operate machinery until you know how RAZAGIN affects you.

3. How to take RAZAGIN

Always take RAZAGIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose of RAZAGIN is 1 tablet of 1 mg taken by mouth once daily. RAZAGIN may be taken with or without food. Swallow the tablet with a glass of water.

Your doctor will tell you for how long you should continue to take RAZAGIN.

If you have the impression that the effect of RAZAGIN is too strong or too weak, talk to your doctor or pharmacist.

If you take more RAZAGIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take the remaining tablets with you so that the doctor will know what the patient has taken. You may require medical attention.

Symptoms reported following overdose of RAZAGIN included slightly euphoric mood (light form of mania), extremely high blood pressure and serotonin syndrome (any combination of hallucinations, fever, restlessness, tremor and sweating).

If you forget to take RAZAGIN

Do not take a double dose of RAZAGIN to make up for forgotten individual doses.

Always try taking RAZAGIN at the same time each day. If you forget to take a RAZAGIN tablet, take the next dose normally, when it is time to take it.

If you stop taking RAZAGIN

Do not stop taking RAZAGIN unless your doctor tells you to.

4. POSSIBLE SIDE EFFECTS

RAZAGIN can have side effects.

Not all side effects reported for RAZAGIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RAZAGIN, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking RAZAGIN and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- skin rash with blistering vesicles (small fluid-filled sacs), itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RAZAGIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe chest pain, severe headache, blurred vision, nausea, severe anxiety (hypertensive crisis)
- sudden numbness or weakness of face, arm or leg, confusion, dizziness (stroke)
- if you develop unusual behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive shopping or spending, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts (impulse control disorders) (see section 2)
- if you see or hear things which are not there (hallucinations)
- any combination of hallucinations, fever, restlessness, tremor and sweating (serotonin syndrome)
- if you notice any suspicious skin changes because there is a higher risk of skin cancer (not exclusively melanoma) in patients with Parkinson's disease.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- fever, flu (influenza), general feeling of being unwell (malaise)
- abnormal results of blood tests (leukopenia)
- allergy
- depression
- headache
- bloodshot eyes (conjunctivitis)
- sensation of feeling off balance (vertigo)
- chest pain (angina)
- runny nose (rhinitis)

- abdominal pain, constipation, flatulence, dyspepsia, dry mouth, decreased appetite
- irritation of the skin (dermatitis), contact dermatitis (a rash on your skin when you touch or have a reaction to a certain substance)
- musculoskeletal pain, neck pain, joint inflammation (arthritis), back pain, pain in the wrists (arthralgia)
- a painful condition affecting the tendons on the thumb side of your wrist (tenosynovitis)
- urinary urgency
- abnormal dreams, hallucinations (seeing and hearing things that do not exist)
- abnormal movements (dyskinesia), difficulty in muscular coordination (ataxia), balance disorder
- numbness and muscle weakness of the hand (carpal tunnel syndrome)
- low blood pressure when rising to a standing position with symptoms like dizziness/light-headedness (orthostatic hypotension)
- nausea, vomiting
- rash
- decreased weight
- falls.

Less frequent side effects

- Stroke (cerebrovascular accident)
- Heart attack (myocardial infarction)

Frequency not known

- Excessive drowsiness
- Sudden onset of sleep
- High blood pressure

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA on the SAHPRA website: https://www.sahpra.org.za/health-products-vigilance. By reporting side effects, you can help provide more information on the safety of RAZAGIN.

5. How to store RAZAGIN

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the tablet strips in the carton.

Do not use if the pack is damaged or shows signs of tampering.

Do not store in bathroom.

Do not use after the expiry date stated on the label / carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RAZAGIN contains

- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as rasagiline tartrate).
- The other ingredients are microcrystalline cellulose (E460), pregelatinised maize starch, colloidal anhydrous starch, malic acid (E296), stearic acid (E570).

What RAZAGIN looks like and contents of the pack

RAZAGIN tablets are presented as:

White to off-white, round, flat, bevelled tablets debossed with “1” on one side and plain on the other.

RAZAGIN tablets are packed in Aluminium-OPA/Alu/PVC blister packs of 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of the Registration certificate

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Access to the corresponding Professional Information

For a copy of the Professional Information (PI), please contact enquiries@unicornpharma.co.za.

RAZ/L/A