PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

RASAPAR 1 mg tablets

Rasagiline

Sugar free

Read all of this leaflet carefully before you start taking RASAPAR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, pelase ask your doctor, pharmacist, nurse or other health care provider.
- RASAPAR 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 RASAPAR is and what it is used for**
2. **What you need to know before you take RASAPAR**
3. **How to take RASAPAR**
4. **Possible side effects**
5. **How to store RASAPAR**
6. **Contents of the pack and other information**

1. What RASAPAR is and what it is used for

RASAPAR contains the active substance rasagiline. Rasapar is a monoamine oxidase (MAO) inhibitor and is used for the treatment of Parkinson's disease in adults.

RASAPAR can be used together with or without levodopa (another medicine that is used to treat Parkinson's disease). With Parkinson's disease, there is a loss of cells that produce dopamine in the brain. Dopamine is a chemical substance in the brain involved in movement control. RASAPAR helps to increase and sustain levels of dopamine in the brain.

2. What you need to know before you take RASAPAR

Do not take RASAPAR:

- If you are hypersensitive (allergic) to rasagiline or any of the other ingredients of RASAPAR (listed in section 6 of this leaflet).
- If you have moderate to severe liver impairment or liver insufficiency.

Do not take the following medicines while taking RASAPAR:

- Other MAO inhibitors (e.g. for treatment of depression or Parkinson's disease, or used for any other indication), including medicines and natural products available without prescription, e.g. St John's wort.
- Pethidine (a strong pain killer).

You must wait at least 14 days after stopping RASAPAR treatment before starting treatment with MAO inhibitors or pethidine. Also see section 'Other medicines and RASAPAR'.

Warnings and precautions

Tell your doctor or healthcare professional before taking RASAPAR:

- If you have any liver problems.
- About any suspicious skin changes (see section 4).
- If you or your family/caregiver notices that you are developing unusual behaviours where you

cannot resist the impulse, urges or cravings to carry out certain activities that are harmful or detrimental to yourself or others. These are called impulse control disorders. In patients taking RASAPAR 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 observed. Your doctor may need to adjust or stop your dose (see section 4).

- If you are smoking or intend to stop smoking. Smoking could decrease the amount of RASAPAR in the blood.

RASAPAR 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'.

Children and adolescents

There is no relevant use of RASAPAR in children and adolescents. Therefore, RASAPAR is not recommended for use under the age of 18.

Other medicines and RASAPAR

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

Do not take RASAPAR with the following medicines:

- Other MOA inhibitors e.g. selegiline (used to treat parkinsonism), hydralazine and moclobemide (antidepressants), linezolid (antibiotic).
- St John's wort (antidepressant).
- Pethidine (a strong pain killer).

The use of RASAPAR together with the antidepressants containing fluoxetine or fluvoxamine should be avoided. If you are starting treatment with RASAPAR, you should wait at least 5 weeks after

stopping fluoxetine treatment. If you are starting treatment with fluoxetine or fluvoxamine, you should wait at least 14 days after stopping RASAPAR treatment.

Tell your doctor if you are taking:

- Certain antidepressants (selective serotonin reuptake inhibitors, selective serotonin-norepinephrine reuptake inhibitors, tricyclic or tetracyclic antidepressants).
- The antibiotic ciprofloxacin used against infections.
- The cough suppressant dextromethorphan.
- Sympathomimetics such as those present in eye drops, nasal and oral decongestants and cold medicines containing ephedrine or pseudoephedrine.

RASAPAR with food and drink

RASAPAR may be taken with or without food.

Pregnancy and breastfeeding

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 health care provider for advice before taking RASAPAR.

You should avoid RASAPAR during pregnancy, as the effects of RASAPAR on pregnancy and the unborn child is not known.

Driving and using machines

Ask your doctor for advice before you drive or operate machines, since Parkinson’s disease itself as well as the treatment with RASAPAR may influence your ability to do so.

RASAPAR can make you feel dizzy or drowsy. It can also cause episodes of sudden sleep onset. This might be enhanced 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 drink alcohol while taking RASAPAR.

If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking RASAPAR, do not drive or operate machinery (see section 2).

3. How to take RASAPAR

Do not share any medicines prescribed for you with any other person.
Always take RASAPAR exactly as your doctor has told you. Check with your doctor if you are not sure.
The usual dose of RASAPAR is one tablet of 1 mg taken orally once a day.
RASAPAR may be taken with or without food.

Your doctor will tell you how long your treatment with RASAPAR will last.
If you have the impression that the effect of RASAPAR is too strong or too weak, tell your doctor or pharmacist.

If you take more RASAPAR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and your remaining tablets with you so the doctor can see what you have taken.

If you forget to take RASAPAR

Do not take a double dose to make up for a forgotten dose. Take the next dose as usual, when it is time to take it.

If you stop taking RASAPAR

Do not stop taking RASAPAR without first talking to your doctor.

4. Possible side effects

RASAPAR can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RASAPAR. 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:

- Chest pain, chest discomfort, trouble breathing.
- Sudden numbness or weakness of the face, arm or leg, especially on one side of the body, confusion, trouble speaking, trouble seeing in one or both eyes, dizziness, loss of balance or severe headache.

- 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 such as darkening of skin, changes in the skin texture, sores that do not heal, itchiness, tenderness or pain (see section 2).

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

Tell your doctor if you notice any of the following:

Side effects that may occur frequently:

- Headache, low mood.
- Abnormal dreams.
- Sensation of spinning dizziness.
- Flu, fever, runny nose.
- Abnormal blood test results.
- Eye inflammation causing redness, itching and tearing of the eyes.
- Flatulence, abdominal pain, decreased appetite, anorexia, constipation, dry mouth, nausea and vomiting.
- Skin irritation, rash.
- Low blood pressure when rising to a standing position with symptoms like dizziness or light-headedness (orthostatic hypotension).
- Joint, neck and muscle pain.
- Painful inflammation in the hands, wrists and feet, with swelling and difficulty moving.
- Sudden urge to urinate.
- General feeling of being unwell (malaise).
- Uncontrolled, involuntary muscle movement, muscle contractions that cause twisting movements.
- Feeling unsteady, dizzy or off balance, fall

- Decreased weight.
- Numbness and muscle weakness of the hand.

Side effects that may occur less frequently:

- Blistering rash.

Side effects that may occur with unknown frequency:

- Elevated blood pressure (hypertension).
- Excessive drowsiness.
- Sudden onset of sleep.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of RASAPAR.

5. How to store RASAPAR

- Store at or below 25 °C.
- Keep blister strips in carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RASAPAR contains

The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as tartrate).

The other ingredients are microcrystalline cellulose, pregelatinised starch, colloidal anhydrous silica, malic acid and stearic acid.

What RASAPAR looks like and contents of the pack

White to off-white, round, flat, bevelled tablets debossed with “1” on one side and plain on the other side. The diameter of the tablet is 8,5 mm ± 0,4 mm.

Silver aluminium-OPA/alu/PVC blister strips.

Pack sizes: 7, 10, 28, 30 or 100 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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