

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

MACLORAS TABLETS TABLETS

Rasagiline mesylate

Sugar free

Read all of this leaflet carefully before you start taking **MACLORAS TABLETS**

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

1. What **MACLORAS TABLETS** is and what it is used for

MACLORAS TABLETS is a medicine which contains rasagiline mesylate and belongs to a class of medicines called anti-parkinsonism.

MACLORAS TABLETS is used for the treatment of Parkinson's disease (PD). Parkinson's Disease causes a loss of cells that make dopamine. Dopamine is a chemical in the brain that controls

movement. It can be used together with or without levodopa (another medicine which is used to treat Parkinson's disease)

2. What you need to know before you take **MACLORAS TABLETS**

Do not take **MACLORAS TABLETS:**

- If you are allergic to rasagiline or any of the other ingredients of this medicine, listed in section 6.
- If you have moderate or severe liver disease.
- If you are currently taking following medicines
 - o monoamine oxidase (MAO) inhibitor (used for the treatment of depression or Parkinson's disease)
 - o pethidine (a strong pain killer)
 - o fluoxetine or fluvoxamine (an antidepressant)
 - o including medicinal or natural products without prescription, eg. St John's Wort

You must wait 14 days after stopping **{PRODUCT NAME}** treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions

Tell your doctor before taking **MACLORAS TABLETS**

If you have any suspicious skin changes. Treatment with **MACLORAS TABLETS** may possibly increase the risk of cancer.

If you or your family notice any behavioural changes (failure to resist a temptation, an urge, compulsive behaviour, unwanted disturbing thoughts and increased sexual desire)

feeling sleepy or falling asleep during daily activities

if you have mild liver insufficiency

If you have any area of skin that is different to the surrounding skin, such as a lump or sore or anything looking different

Use in children and adolescents

The use of **MACLORAS TABLETS** in children and adolescents (below the age of 18 years) is not recommended.

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Other medicines and MACLORAS TABLETS

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

Tell your doctor or pharmacist if you are taking any of the following medicines:

- monoamine oxidase (MAO) inhibitor (used for the treatment of depression or Parkinson's disease)
- pethidine (a strong pain killer)
- fluoxetine or fluvoxamine (an antidepressant).

Keep interval at least of five weeks after stopping treatment of fluoxetine or fluvoxamine (an antidepressant) then start treatment of **MACLORAS TABLETS**.

Wait at least for 14 days after discontinuation of **MACLORAS TABLETS** and then start treatment with antidepressant (including MAO inhibitor, fluoxetine or fluvoxamine) or strong pain killer (pethidine).

- Dextromethorphan (a cough suppressant)
- ephedrine or pseudoephedrine (nasal and oral decongestant or medicine used relieve congestion)
- selective serotonin reuptake inhibitors (SSRIs) (medicines used in the treatment of major depressive disorder), tricyclic, tetracyclic antidepressants (medicines used for the treatment of depression e.g. amitriptyline, amoxapine)
- levodopa or entacapone (another medicine used to treat Parkinson's disease)
- Ciprofloxacin (an antibiotic medicine used to treat various infections)
- If you are smoking as the effect of **MACLORAS TABLETS** may decrease due to smoking.

MACLORAS TABLETS with food and drink:

MACLORAS TABLETS may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **MACLORAS TABLETS**.

Do not take **MACLORAS TABLETS** if you are pregnant, are considering becoming pregnant or are breastfeeding.

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Driving and using machines

MACLORAS TABLETS may have major influence on ability to drive and use machine in patients experiencing sudden sleep episodes.

Use with caution while driving or operating hazardous machinery including motor vehicles, until you know how **MACLORAS TABLETS** affects you.

If you have already experienced somnolence (feeling sleepy or sleeping for long periods) before taking **MACLORAS TABLETS** and falling asleep during daily activities, you should not drive, operate machinery or work at heights during treatment with **MACLORAS TABLETS**.

If you are using **MACLORAS TABLETS** and taking anti-depressants (benzodiazepines) or ciprofloxacin (medicine which may increase the effect of **MACLORAS TABLETS**) or alcohol, it may increase sleepiness hence take special care while driving and using machinery

3. How to take MACLORAS TABLETS

Do not share medicines prescribed for you with any other person.

Always take **MACLORAS TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

MACLORAS TABLETS must be taken orally, one tablet daily with or without levodopa and with or without food.

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

If you take more MACLORAS TABLETS than you should

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

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If you forget to take MACLORAS TABLETS

It is important to take your **MACLORAS TABLETS** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking MACLORAS TABLETS

If **MACLORAS TABLETS** is stopped earlier than your doctor has prescribed, your symptoms may return or worsen. Always take **MACLORAS TABLETS** for as long as your doctor has prescribed.

4 Possible side effects

MACLORAS TABLETS can have side effects.

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

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

- myocardial infarction (chest pain with discomfort in arms, back, neck, jaw and shoulders)
- Cerebrovascular accident (stroke include trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg)
- allergic reactions (Hypersensitivity)

These are all very serious side effects. If you have them, you may have had a serious reaction to **MACLORAS TABLETS**. 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
- Angina pectoris (a type of chest pain caused by reduced blood flow to the heart)

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- skin lesions or rashes (part of skin that has an abnormal lump or growth compared to the skin around it may lead to skin cancer)
- abdominal pain

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

Tell your doctor if you notice any of the following:

Frequent

- orthostatic hypotension (person's blood pressure falls when suddenly standing up from a lying or sitting position)
- leucopenia (a reduction in the number of white cells in the blood)
- depression
- vertigo (a sensation of spinning around and losing one's balance)
- dyskinesia (abnormality or impairment of voluntary movement)
- dystonia (abnormal muscle tone resulting in muscular spasm and abnormal posture)
- skin carcinoma (skin cancer)
- dermatitis (part of skin becomes red, swollen and sometimes with small blisters)
- vesiculobullous rash (fluid-filled lesions)
- Fever
- neck pain
- abnormal dreams
- hallucinations (an experience involving the apparent perception of something not present)
- constipation
- vomiting
- dry mouth
- Nausea
- abdominal pain
- flatulence
- decreased appetite
- weight loss

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- arthralgia (pain in a joint)
- arthritis (Inflammation of one or more joints, causing pain and stiffness)
- urinary urgency
- Rhinitis
- conjunctivitis (Inflammation or infection of the outer membrane of the eyeball and the inner eyelid)
- headache
- flu syndrome (fever, cough, sore throat, runny nose, fatigue)
- malaise (a general feeling of discomfort, illness, or unease)
- carpal tunnel syndrome (numbness and tingling in the hand and arms)
- balance disorder and fall

Less frequent:

- Confusion

Frequency unknown

- serotonin syndrome (symptoms includes high body temperature, agitation, increased reflexes, tremor, sweating, dilated pupils, and diarrhoea)
- excessive daytime sleepiness and sudden sleep episodes
- impulse control disorder (failure to resist a temptation, an urge, compulsive behaviour increased sexual desire)
- hypertension (increased blood pressure)

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

Should your general health worsen or if you experience any untoward effects while taking

MACLORAS TABLETS; please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse**

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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 **MACLORAS TABLETS**.

5. How to store MACLORAS TABLETS

Store at or below 25 °C.

Protect from moisture.

Do not store in a refrigerator.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist.

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

6. Contents of pack and other information

What MACLORAS TABLETS contains

The active ingredient is rasagiline mesylate.

Sugar free

The other ingredients are:

Microcrystalline cellulose

Corn starch

Colloidal silicon dioxide

Anhydrous citric acid

Pregelatinized starch

Talc

Stearic acid

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What MACLORAS TABLETS looks like and contents of the pack

MACLORAS TABLETS: White to off-white, round, flat bevelled edged tablets debossed with “C13” on one side and plain on the other side.

Contents of the pack:

Tablets are packed in a round white 60 HDPE container with a silica gel sachet and closed with a white child resistant closure packed in an outer carton. Pack sizes include 28's, 30's tablets.

Tablets are packed in aluminium foil laminated on one side and laminated to PVC on the other side.

Pack sizes include 10's tablets or 28's tablets.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

1 Cussonia Drive,

Bassonia Rock Ext 12

Alberton

Gauteng

This leaflet was last revised in

24 October 2023

Registration numbers

MACLORAS TABLETS: 56/5.4.1/0506.505

Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com> or email macleodsrsa@macleodspharma.com or contact 011 682 1169

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