

Masilect 1

Rasagiline Tablets 1 mg

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What Masilect 1 used for

Masilect 1 tablet is used to treat the symptoms of Parkinson's disease. It can be taken with or without dopamine agonist or levodopa therapy.

Parkinson's disease is a condition of the brain that mainly affects body movement. The three main symptoms of Parkinson's disease are:

- Shaking (tremor)
- Muscle stiffness
- Slow and unsteady movement

In Parkinson's disease, there is a loss of cells producing dopamine in certain areas in the brain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

How Masilect 1 works

Masilect 1 contains the active ingredient rasagiline (as mesilate). Masilect 1 is a monoamine oxidase (MAO) inhibitor.

Masilect 1 works by increasing and maintaining the level of dopamine in your brain which will decrease symptoms of Parkinson's disease.

Before you use Masilect 1

- When you must not use it
- you are allergic to rasagiline, or any of the ingredients listed at the end of this leaflet.

If you have an allergic reaction you may get a skin rash, have difficulty in breathing, get symptoms of hay fever or feel faint.

Always check the ingredients to make sure you can use this medicine.

- you have a problem with your liver.
- it is after the expiry date (EXP) printed on the pack. It may not work as well.
- the packaging is torn or shows signs of having been tampered with.
- you do not understand the instructions on the label, ask your doctor or pharmacist for help.
- you are not sure whether you should start taking this medicine, talk to your doctor.

Pregnancy and lactation

Tell your doctor if you are pregnant or intend to become pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor can discuss with you the risks and benefits involved.

Children under 18 years

- Masilect 1 should not be given to children under 18 years of age as there is no specific information about such use. Always ask your doctor before giving medicines to children.

- Before you start to use it

Check with your doctor if you smoke. Nicotine can affect the levels of rasagiline in your body.

Inform your doctor if you notice any suspicious skin changes. Treatment with Masilect 1 may possibly increase the risk of skin cancer.

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 Side effects.

- Taking other medicines

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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.

If you are already taking Masilect 1, do not take another medicine called:

- monoamine oxidase inhibitors (MAOI), whether used to treat depression, Parkinson's disease or any other condition.
- Other medicinal and natural products without prescription which have MAOI activity (e.g. St. John's Wort).
- pethidine, a strong pain killer.
- ciprofloxacin, an antibiotic used to treat infection.

Wait at least 14 days between stopping Masilect 1 and starting your MAOI medicine or pethidine.

The following medicines require specific medical advice before being taken together with Masilect 1:

- medicines used to treat depression, anxiety, panic disorder, obsessive compulsive disorder or pre-menstrual dysphoric disorders. Examples of such medicines include selective serotonin reuptake inhibitors (SSRIs), tricyclic and tetracyclic antidepressants
- other medicines used to treat depression called fluoxetine and fluvoxamine.
- Wait at least 5 weeks between stopping fluoxetine treatment and starting treatment with Masilect

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1, and 14 days between stopping Masilect 1 treatment and starting treatment with fluoxetine or fluvoxamine.

- dextromethorphan, a medicine for cough, and substances with sympathomimetic activity such as those present in 'cold and flu' oral tablets and nasal drops containing ephedrine or pseudoephedrine.
- clozapine, a medicine used to treat schizophrenia.
- other medicines used to treat symptoms of Parkinson's disease.

Your doctor or pharmacist can tell you what to do if you are taking this or any other medicines.

If you have not told your doctor about any of these things, tell them before you take Masilect 1.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Masilect 1.

How to use Masilect 1

- How much to use

- The usual dose for Masilect 1 is one tablet of 1 mg taken orally once a day.
- Your doctor will tell you how much Masilect 1 to take each day. Take the amount your doctor tells you to.
- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

- When to use 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.

- Swallow the tablets whole with a full glass of water.

- Masilect 1 can be taken with or without food.

- How long to use it

Do not stop taking this medicine without first checking with your doctor.

- If you forget to use it

Masilect 1 should be used regularly at the same time each day. If you miss your dose at the usual time, and 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 it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed. This may increase the risk of side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

- If you use too much (overdose)

If you think that you have used too much Masilect 1, you may need urgent medical attention.

You should immediately:

- 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.

While you are using Masilect 1

- Things you must do

Tell your doctor if you notice any unusual skin lumps or moles which are new or have changed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Masilect 1, especially if you are being started on any new medicines.

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- become pregnant while taking Masilect 1. Remind any doctor, dentist or pharmacist you visit that you are using Masilect 1.
- Things you must not do
- Do not take Masilect 1 to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if their symptoms seem similar to yours.
- Do not drive, operate machinery or work at heights during treatment if you have fallen asleep without warning, prior to the use of Masilect 1.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from a bed or chair, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Scientific evidence suggests that Parkinson's disease is associated with a higher risk of skin cancer, (including melanoma). During the development (placebo- controlled clinical trials), melanoma was observed in both Rasagiline 1 mg- and placebo-treated patients (around 0.5% vs 0.2% respectively). People with Parkinson's disease, including those taking Rasagiline 1 mg, should undergo periodic examination of the skin.

Eating excessive amounts of foods rich in tyramine (e.g.: aged cheese, red wine) while you are taking Masilect 1 could very rarely cause an

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increase in your blood pressure and should be avoided. If you do eat these foods while you are taking Masilect 1 and do not feel well, you should contact your doctor. Your doctor or pharmacist can advise you on what foods are rich in tyramine and what your risk of having a reaction may be.

- Things to be careful of

Driving and using machines

Be careful before you drive or use any machines or tools until you know how Masilect 1 affects you.

Masilect 1 may cause you to feel sleepy in the daytime during daily activities.

Drinking alcohol

Tell your doctor if you drink alcohol. Be careful when drinking alcohol while taking this medicine.

Side effects

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. 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
- headache - flu-like syndrome - malaise - neck pain - indigestion - joint pain - depression - eye inflammation - abdominal pain - accidental injury (primarily falls) - dizziness when you stand up	Speak to your doctor if you have any of these less serious side effects and they worry you.

due to low blood pressure - constipation - vomiting - weight loss - difficulty in moving normally - obsessive thoughts or impulsive behaviour	
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Contact your doctor if you notice any suspicious skin changes because there may be an increased risk of skin cancer (melanoma) with the use of this medicine.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of Masilect 1

- Storage

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle after EXP.
- Store below 30°C.
- If the tablets become discoloured or show any signs of deterioration, seek the advice of your pharmacist who will advise you what to do.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These

measures will help protect the environment.

Product Description

- What it looks like

Masilect 1 tablet are presented as white to off white, circular, flat faced beveled edge, uncoated tablets, "1" debossed on one face with the other face plain.

- Ingredients

- Active ingredient(s)

Rasagiline mesylate 1.56 mg (equivalent to rasagiline 1 mg)

- Inactive ingredients

Microcrystalline cellulose/Avicel PH 101, Corn Starch, Pregelatinised starch/Starch 1500, Citric Acid Monohydrate, Colloidal Silicon Dioxide (Aerosil 200 Pharma), Talc, Stearic Acid (Speziol L2SM Pharma)

- MAL number:

MALxxxxxxx

Manufacturer

Micro Labs Limited

Plot No. S.155 to S.159 & N1 Verna Industrial Estate, Phase III & Phase IV, Verna Salcette Goa, IN-403722 India

Product Registration Holder

Mansa Healthcare Sdn Bhd

B-05-3A, 3 Two Square No 2, Jalan 19/1, 46300 Petaling Jaya, Selangor, Malaysia

Date of revision

8-May-2026

Serial Number

NPRA (R1) 26/001