

RASALECT™

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 RASALECT?

RASALECT contains the active ingredient rasagiline (as mesilate). RASALECT is used to treat the symptoms of Parkinson's disease. It can be taken with or without dopamine agonist or levodopa therapy.

For more information, see Section [1. Why am I using RASALECT?](#) in the full CMI.

2. What should I know before I use RASALECT?

Do not use if you have ever had an allergic reaction to rasagiline 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 RASALECT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RASALECT 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 RASALECT?

- The usual dose for RASALECT is one tablet of 1 mg taken orally once a day.
- Swallow the tablets whole with a full glass of water.
- RASALECT can be taken with or without food.

More instructions can be found in Section [4. How do I use RASALECT?](#) in the full CMI.

5. What should I know while using RASALECT?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RASALECT.• Tell your doctor if you notice any unusual skin lumps or moles

	<p>which are new or have changed.</p>
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop taking this medicine without first checking with your doctor. ● Do not take RASALECT 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.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Do not drive, operate machinery or work at heights during treatment if you have fallen asleep without warning, prior to the use of RASALECT. ● Be careful before you drive or use any machines or tools until you know how RASALECT affects you.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Be careful when drinking alcohol while you are taking this medicine.]

Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C• Keep RASALECT in the blister pack until it is time to take it.
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For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

For information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RASALECT[®] (ra-SA-ji-leen MES-i-late)

Active ingredient(s): Rasagiline (as mesilate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using RASALECT. **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 RASALECT.**

Where to find information in this leaflet:

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

1. Why am I using RASALECT?

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

RASALECT 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.

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

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.

2. What should I know before I use RASALECT?

Warnings

Do not use RASALECT if:

- **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 hayfever 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.

Check with your doctor if you:

- have a problem with your liver
- if you smoke. Nicotine can affect the amount of rasagiline that is in your body.

You should speak with your doctor about any suspicious skin changes. Treatment with RASALECT 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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

- RASALECT 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.

3. What if I am 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 RASALECT, 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 RASALECT and starting your MAOI medicine or pethidine

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

- 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 RASALECT, and 14 days between stopping RASALECT treatment and starting treatment with fluoxetine or fluvoxamine.

- dextromethorphan, a medicine for cough.
- 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 RASALECT.

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

4. How do I use RASALECT?

How much to take

- The usual dose for RASALECT is one tablet of 1 mg taken orally once a day.
- Your doctor will tell you how much RASALECT 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 take RASALECT

- 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.
- RASALECT can be taken with or without food.

If you forget to take RASALECT

RASALECT 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 chance of you getting an unwanted 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 RASALECT

If you think that you have used too much RASALECT, 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 RASALECT?

Things you should 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 RASALECT, 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 RASALECT.

Remind any doctor, dentist or pharmacist you visit that you are using RASALECT.

Things you should not do

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

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 RASALECT- and placebo-treated patients (around 0.5% vs 0.2% respectively). People with Parkinson's disease, including those taking RASALECT, should undergo periodic examination of the skin.

Eating excessive amounts of foods rich in tyramine (eg. aged cheese, red wine) while you are taking RASALECT could very rarely cause an increase in your blood pressure and should be avoided. If you do eat these foods while you are taking RASALECT and do not feel well, you should contact your treating doctor. Your treating doctor or pharmacist can advise you on what foods are rich in tyramine and what your risk of having a reaction may be.

Driving or using machines

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

RASALECT 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 you are taking this medicine.

Looking after your medicine

- Store below 25°C
- Keep RASALECT in the blister pack until it is time to take it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it 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.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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
<ul style="list-style-type: none">• headache• flu syndrome• malaise• neck pain• indigestion• joint pain• depression• eye inflammation• abdominal pain	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● accidental injury (primarily falls) ● dizziness when you stand up due to low blood pressure ● constipation ● vomiting ● weight loss ● difficulty in moving normally ● obsessive thoughts or impulsive behaviour 	

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.

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. It is not addictive.

What RASALECT contains

Active ingredient (main ingredient)	1 mg of rasagiline (as rasagiline mesilate).t]
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● mannitol● colloidal anhydrous silica● maize starch● pregelatinised maize starch● stearic acid*● purified talc

*** vegetable origin**

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

What RASALECT looks like

RASALECT is a white to off-white, round, flat, bevelled tablet, debossed with “GIL” and “1” underneath on one side

1mg (blister): AUST R 319000

Who distributes RASALECT

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Rd

Macquarie Park, NSW, 2113

Australia

Telephone: 1800 288 382

This leaflet was prepared in June 2021.

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