

AZILECT

Rasagiline mesilate (ra-SA-ji-leen MES-i-late)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Azilect. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Azilect against the benefits they expect it will have for you.

If you have any concerns about taking this medicine ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again

What Azilect is used for

Azilect 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.

Azilect 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.

This medicine is available only with a doctor's prescription. It is not addictive.

Azilect 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 take Azilect

When you must not take it.

Do not take Azilect if you have ever had an allergic reaction 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.

If you are already taking Azilect, 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 Azilect and starting your MAOI medicine or pethidine.

Do not take Azilect if you have a problem with your liver.

Do not take Azilect after the expiry date (EXP) printed on the pack.

It may have not work as well

Do not take Azilect if the packaging is torn or shows signs of having been tampered with.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor if you have a problem with your liver.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you smoke.

Nicotine can affect the amount of rasagiline that is in your body.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a

prescription from a pharmacy, supermarket or health food shop.

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

- 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 Azilect, and 14 days between stopping Azilect 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 Azilect.

How to take Azilect

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Azilect to take each day. Take the amount your doctor tells you to.

The usual dose for Azilect is one tablet of 1 mg taken orally once a day.

How to take it

Swallow the tablets whole with a full glass of water.

Azilect can be taken with or without food.

When to take 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.

How long to take it

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

If you forget to take it

If 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 that 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 take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (Telephone 13 11 26) for advice, or go to the Accident and Emergency department at your nearest hospital if you think that you or anyone else may have taken too much Azilect. Do this even if there are no signs

of discomfort or poisoning. Keep telephone numbers for these places handy.

While you are taking Azilect

Things you must do

Tell your doctor immediately if you become pregnant while taking Azilect.

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

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

Things you must not do

Do not take Azilect 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 Azilect.

Things to be aware of

As with any new medicine, make sure you know how Azilect affects you before you drive or operate machinery.

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

Be careful when drinking alcohol while you are taking this medicine.

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 Azilect- and placebo-treated patients (around 0.5% vs 0.2% respectively). People with Parkinson's disease, including those taking Azilect, 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 Azilect could very rarely cause an increase in your blood pressure and should be avoided. If you do eat these foods while you are taking Azilect 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Azilect.

This medicine helps most people with Parkinson's disease, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- headache
- flu syndrome
- malaise
- neck pain
- indigestion
- joint pain

- depression
- eye inflammation
- abdominal pain
- 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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Some people may get other side effects while using Azilect.

After taking Azilect

Storage

Keep Azilect in the blister pack until it is time to take them.

Keep Azilect in a cool dry place where the temperature stays below 25°C.

Do not store Azilect or any other medicine in the bathroom or near a sink or stove. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Azilect 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.

Disposal

Dispose of the tablets where children cannot reach them.

Ask your pharmacist what to do with any Azilect you may have left over if your doctor tells you to stop using it, or you find that the tablets have passed the expiry date.

Azilect description

What Azilect tablets look like

White to off-white, round, flat, bevelled tablets, debossed with "GIL" and "1" underneath on one side.

Ingredients

Azilect tablets contain 1 mg of rasagiline (as rasagiline mesilate).

The tablets also contain:

- mannitol
- silica - colloidal anhydrous
- starch maize
- starch-pregelatinised maize
- stearic acid*
- talc-purified

* Vegetable origin.

Manufacturer

Azilect is supplied in Australia by:

Teva Pharma Australia Pty Ltd

37 Epping Rd

Macquarie Park, NSW 2113

Australia

Telephone: 1800 288 382

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Australian Registration Numbers are:

1mg (blister): AUST R 170172

1mg (bottle): AUST R 172457

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