Rasagiline (Azilect) for Parkinson’s disease

This Medicine Update is for people with Parkinson’s disease who are taking, or thinking about taking, rasagiline.

Summary

Rasagiline is a medicine that has recently been made available in Australia for the treatment of Parkinson’s disease. Like other medicines for Parkinson’s disease, rasagiline treats the symptoms but does not cure the condition.

If you are just starting treatment, rasagiline may be prescribed on its own. In the later stages of Parkinson’s disease, it may be prescribed in addition to levodopa.

Although rasagiline is less effective than levodopa at controlling the symptoms of Parkinson’s disease, over a period of time the effectiveness of levodopa wears off. Also, you may develop unpredictable twisting, jerking and dancing movements (known as dyskinesia) as a side effect of levodopa.

Rasagiline can be added to levodopa therapy to extend the length of time that treatment is effective, and reduce the amount of levodopa you need to take each day.

When making a decision between rasagiline and other medicines, your doctor will consider how far your Parkinson’s disease has advanced and the need to balance control of your symptoms with the potential side effects of the different medicines.

www.nps.org.au/medicineupdate

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Asking the right questions about new medicines

What is Medicine Update?
Medicine Update provides independent information about new medicines and new listings on the PBS. It tells you about the possible benefits and harms of new medicines, who can and can’t use them, and some of the other treatment options available.

How to use Medicine Update
Medicine Update is a tool to help you understand your treatment choices and to discuss them with your doctor. Medicine Update doesn’t describe all possible side effects, precautions, or interactions with other medicines — so you should always read the consumer medicine information (CMI) leaflet (see back page).

Who is it for?
Medicine Update is for anyone who is starting this medicine or thinking of starting it, and their carers.

Where does Medicine Update come from?
Medicine Update is written by the National Prescribing Service Limited (NPS) in consultation with consumers and health professionals. NPS is an independent, non-profit, government-funded organisation.

This information is not intended to take the place of medical advice and you should seek advice from a qualified health professional. Reasonable care is taken to ensure that this information is accurate at the date of creation. Where permitted by law, NPS disclaims all liability (including for negligence) for any loss, damage or injury resulting from reliance on or use of this information.
1. What rasagiline is

The active ingredient of this medicine is rasagiline (pronounced ra-SA-ji-leen). It is also known by the brand name Azilect.

2. What rasagiline is for

Rasagiline is used to treat the symptoms of Parkinson's disease. Parkinson's disease is a condition of the brain that affects body movement.

The main symptoms of Parkinson's disease are:
- muscle stiffness or rigidity
- tremor, or shakiness, especially of the hands
- difficulty starting to walk or making other movements
- slowing down of movement
- problems with speech.

These symptoms tend to fluctuate throughout the day and their intensity can vary from person to person.

As with other medicines for Parkinson's disease, rasagiline is not a cure, nor does it stop the progression of Parkinson's disease.

3. Who can take rasagiline

Rasagiline can be taken on its own, or in addition to another medicine called levodopa.

Rasagiline is not suitable if you:
- have a problem with your liver
- are taking certain antidepressant medicines, including St John’s wort
- are taking any other medicine in the same class as rasagiline (a monoamine oxidase type B [MAO-B] inhibitor) or MAO-inhibitors.

It is not known if rasagiline is suitable for people who have been diagnosed with major depression, as these people were excluded from clinical trials.

Your doctor will take your individual situation into account when helping you decide if rasagiline might be suitable for you.
4. How to take rasagiline

Take one 1 mg rasagiline tablet once a day. Swallow the tablet whole with a full glass of water. You can take rasagiline at any time of day, with or without food.

You will get the most benefit if you take it at the same time each day. This can also help you remember to take it.

If you forget a dose, take it as soon as you remember. Or, if it is almost time for your next dose, skip the one you missed and take the next dose as usual.

Do not take a double dose of rasagiline to make up for the one you missed, as this may increase your chance of experiencing an unwanted side effect.

Do not stop taking rasagiline without discussing it with your doctor.

5. What does rasagiline do?

Many of the symptoms of Parkinson's disease are caused by a lack of dopamine, which is a naturally occurring chemical produced in the brain. When there is too little dopamine, movement is affected.

The different medicines for Parkinson's disease work by either increasing the amount of dopamine in the brain or by stimulating dopamine receptors. Rasagiline increases the amount of dopamine in the brain by preventing it being broken down. It is a type of medicine called a monoamine oxidase type B (MAO-B) inhibitor.

Treatment with rasagiline won't stop your Parkinson's disease progressing, but it can help to reduce the symptoms.

How well does rasagiline work?

In clinical trials, rasagiline taken on its own reduced the symptoms of Parkinson's disease compared with a placebo. People in the trial who were taking rasagiline were able to carry out their daily activities more easily.

In clinical trials with people who were already taking levodopa but experiencing an average of 6 hours 'off' time, taking rasagiline with levodopa reduced their 'off' time. On average, when compared with adding a placebo to the levodopa, the 'off' time was reduced by almost an hour each day.

A clinical trial is a research study conducted with patients that compares one treatment with one or more other treatments, or a placebo, to assess its effectiveness and safety.

To find out more about clinical trials, see What are clinical trials and why are they important? at www.nps.org.au/medicinewise_choices

A placebo, or dummy pill, has no active ingredient. Participants in clinical trials do not usually know whether they are taking the active or dummy medicine.

'Off' time is when a medicine for Parkinson's disease stops being effective and the symptoms reappear. With levodopa, the most commonly used medicine for Parkinson's disease, this tends to happen a few years after beginning treatment, but may start after only a few months. It may occur as an intermittent 'on–off' effect, or more predictably as the effect of each dose wears off, in which case it is also known as 'end-of-dose effect' or 'wearing off'.
6. Important side effects to consider

All medicines may have side effects. Sometimes the side effects are serious but most of the time they’re not.

In clinical trials where people were taking rasagiline on its own, the common side effects most frequently experienced were:
- flu-like symptoms
- indigestion
- joint pain
- depression
- headache.

In clinical trials for rasagiline with people who were already taking levodopa, the common side effects most frequently experienced were:
- unpredictable movements or muscle spasms (dyskinesias)
- dizziness when standing up
- pain (in abdomen, joints, neck)
- weight loss or anorexia
- gastro-intestinal symptoms (indigestion, nausea/vomiting, constipation).

The term common when used to describe the chance of getting a side effect means that between 1% and 10% of people (1 to 10 people in a 100) may get this side effect.

For a more complete list of possible side effects see the consumer medicine information (CMI) leaflet for Azilect.

Ask your doctor about the possible side effects of this medicine before you take it. And always tell them about any changes to your condition if you are taking a new medicine.

You can also discuss side effects with a pharmacist, by calling the Adverse Medicines Event (AME) Line on 1300 134 237 (Mon–Fri, 9am–5pm).

7. What else you should know about rasagiline

Check before taking any other medicine
If you are taking rasagiline, talk to your doctor or pharmacist before taking any other medicine, including those from a supermarket or health food store.

Many antidepressants should not be taken with rasagiline
Many medicines for depression can interact with rasagiline to cause a very rare but potentially fatal condition known as serotonin toxicity (also known as serotonin syndrome). This includes the herbal remedy St John’s wort.

If you have depression or anxiety, discuss your options with your doctor, as there are some antidepressants that can be taken with rasagiline.

Avoid certain cough and cold remedies
Certain cough, cold and flu medicines (including nasal drops and eye drops) should not be taken with rasagiline. Check the labels and avoid medicines that contain:
- dextromethorphan
- ephedrine or pseudoephedrine
- phenylephrine.

An interaction is when another medicine, food or drink (including alcohol) changes how strongly a medicine works, or changes its side effects in some way.

The interaction may be with a food or food supplement, another prescription or over-the-counter medicine, or a natural or herbal remedy.

Use a medicine list to help keep track of the medicines you are taking. Take it with you each time you visit your health professional, or if you go into hospital.

Get an NPS Medicines List as a printed card or app for your iPhone at www.nps.org.au/medicineslist
7. **What else you should know about rasagiline ... continued**

**Other medicines that must not be taken with rasagiline:**
- ciprofloxacin, linezolid (antibiotics)
- cimetidine (for GORD)
- methadone, pethidine, tapentadol and tramadol (strong pain medicines)
- selegiline (Eldepryl, Selgene).

**Avoid excessive amounts of tyramine-rich food**

Tyramine is a substance found in certain foods and drinks, particularly those that are aged, smoked or cured. In rare cases, eating very high amounts of foods rich in tyramine while taking rasagiline can cause a dangerous increase in blood pressure. Food and drink that contains moderate levels of tyramine are not a problem.

Aged cheese is the food most likely to cause a problem. Very high levels of tyramine are also found in some tap or unpasteurised beers. Red wines, particularly Chianti, used to be included in the list of foods to avoid, but they are no longer considered to contain high levels of tyramine.

Seek medical attention if you have been eating these foods while taking rasagiline and develop the following symptoms:
- headache
- nausea or vomiting
- sweating
- fast heartbeat
- dilated pupils.

**Keep a look out for any new or changed moles or unusual skin lumps**

There is some evidence to suggest that people with Parkinson’s disease are at greater risk of skin cancer. Be aware of this and have your skin checked regularly.
8. Other medicines for Parkinson’s disease

There are currently four main groups of medicines used to treat Parkinson’s disease:

**Levodopa**
Levodopa is the medicine most commonly used to treat Parkinson’s disease. It works by replacing naturally occurring dopamine.

Levodopa comes under a number of brand names, each of which includes other active ingredients to help the levodopa work more effectively.

Brands include:
- Kinson
- Madopar
- Sinemet
- Stalevo.

These levodopa medicines can be taken on their own or with other types of medicines for Parkinson’s disease.

**COMT inhibitor**
A COMT inhibitor can be taken with levodopa to increase the amount of levodopa available to the brain:
- entacapone (Comtan).

**Dopamine agonists**
Dopamine agonists work by stimulating dopamine receptors in the brain. This compensates for reduced dopamine levels.

Examples include:
- bromocriptine (Kripton, Parlodel)
- cabergoline (e.g. Bergoline, Cabaser)
- pergolide (Permax)
- pramipexole (Sifrol, Sifrol ER)
- rotigotine (Neupro).

**Monamine oxidase type B (MAO-B) inhibitors**
MAO-B inhibitors work by reducing the breakdown of dopamine in the brain.

There are two types:
- rasagiline (Azilect)
- selegiline (Eldepryl, Selgene).

There are other types of medicines used to treat Parkinson’s disease but, as these are now used less commonly, they are not discussed here.

Talk with your health professional about all the treatment options for Parkinson’s disease.
9. How to decide between rasagiline and other medicines

All medicines for Parkinson’s disease have potential benefits and side effects. Your doctor will be able to help you decide which medicine is most likely to be suitable for you, based on your own situation and preferences.

In the early stages of Parkinson’s disease

Levodopa is the most effective medicine for treating Parkinson’s disease. However, some people develop a distressing side effect known as dyskinesia. This is where they experience unpredictable movements such as jerking, twisting and dancing movements of the arms, legs or face. These may not develop for several years after beginning treatment with levodopa, but they can start after only a few months.

Taking a dopamine agonist or MAO-B inhibitor instead of levodopa in the early stages of Parkinson’s disease can postpone the need for you to start taking levodopa. This can delay the onset of dyskinesia.

Also, the effect of levodopa wears off more quickly the longer it is used and so starting out on another medicine may be a good approach.

Both these factors are particularly likely to be a consideration if you are diagnosed with Parkinson’s disease at a younger age (under 70 years).

In the advanced stages of Parkinson’s disease

As the disease advances and your symptoms become more severe it is likely that you will be prescribed levodopa to effectively control these symptoms.

Over time, the effect of each levodopa dose may start to ‘wear off’ before the next one is due. This means that the stiffness, tremor and slow movements of Parkinson’s disease reappear, sometimes quite strongly. Adding a dopamine agonist or MAO-B inhibitor to your levodopa treatment may reduce the amount of ‘off’ time you experience each day.

If you develop dyskinesia (unpredictable jerking, twisting and dancing movements), adding another medicine can make it possible to adjust your levodopa dose and help lessen this side effect.

Sometimes, however, adding another medicine to levodopa may increase the dyskinesia.
Deciding between rasagiline and a dopamine agonist
Rasagiline — and the other MAO-B inhibitor, selegiline — appears to be less effective than dopamine agonists (e.g. pramipexole) at controlling the symptoms of Parkinson's disease and, when taken with levodopa, at reducing ‘off’ time.

However, dopamine agonists are more likely to cause certain side effects that make them unsuitable for some people. These include:

• compulsive behaviours, such as hypersexuality or pathological gambling
• hallucinations and confusion, typically in older people
• falling asleep, sometimes quite suddenly (sleep attack)
• irreversible problems with the heart or lungs (bromocriptine and pergolide only).

These particular side effects are not known to be a problem with rasagiline.

Deciding between rasagiline and the COMT inhibitor, entacapone
Rasagiline appears to be as effective as entacapone when taken with levodopa. The side effects are also similar although, for some people taking entacapone, diarrhoea is a problem.

10. What does rasagiline cost?

Cost to the Government
The full cost of rasagiline to the Australian Government is:
• 1 mg (30 in pack), $121.59

Each prescription is for a 30-day supply of rasagiline.

Cost to the individual
If you get rasagiline through the Pharmaceutical Benefits Scheme (PBS), the Australian Government pays most of the cost and you will pay only a part, called the co-payment.

At the time of publication, the co-payment for people who are entitled to get rasagiline through the PBS is:
• $35.40 for people without a concession card
• $5.80 for concession card holders.

If you’re not eligible to get rasagiline through the PBS, you will need to pay the full price for a prescription.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian Government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

For more information see www.pbs.gov.au
A healthy lifestyle is important for everyone, but for people with Parkinson’s disease it is essential to have a balanced and nutritious diet with plenty of fibre and fluids. Regular exercise is needed to help maintain muscles and joints.

**Diet**

It is common for people with Parkinson’s disease to lose weight, particularly if they have severe tremor or dyskinesias, or find eating difficult. Smaller more frequent snacks may be easier to manage than three main meals, and high-calorie foods such as milkshakes and desserts can help.

For others, being overweight may be a problem, because Parkinson’s disease can make walking and other activities difficult.

Constipation can also be a concern, because Parkinson’s disease affects nerve cells in the gut. This is why high-fibre foods and plenty of water are particularly important.

A small number of people taking levodopa may find eating a meal containing a lot of protein reduces the effectiveness of the medicine. Although this is not common, you should discuss the possibility with your doctor.

**Exercise**

Exercise is good for everyone and is especially important for people with Parkinson’s disease, as their muscles and joints tend to get stiff and rigid.

Exercise can also provide a chance to socialise. And it can help relieve depression. If you are unsure about the suitability or safety of any exercise, you should discuss it with your doctor or ask for a referral to a physiotherapist.

**Coping with depression**

Depression and anxiety are very common in people with Parkinson’s disease. There’s growing evidence that this is not only a result of being diagnosed with a chronic degenerative disease, but that these conditions are directly due to Parkinson’s disease itself.

It’s important to talk to your doctor if you feel you may be depressed or experience anxiety. While many antidepressant medicines cannot be used at the same time as medicines for Parkinson’s disease, there are still some medicines, as well as other therapies, that can be effective.

For more information on depression and advice on where to get support contact beyondblue (www.beyondblue.org.au). A fact sheet on Parkinson’s disease depression and anxiety is available on their web site.

**Support therapies and services**

As Parkinson’s disease progresses, physiotherapists, occupational therapists and speech therapists can help with strategies and aids to maximise independence. These specialists can help with specific exercises, education and retraining to improve coordination, balance and movement.

For more information about Parkinson’s disease visit www.parkinsons.org.au or call 1800 644 189.

You can also get information and help from the Independent Living Centre. Visit their website, www.ilc.com.au, for contact details of your State or Territory organisation.
Where to find more information

You can find more information in the consumer medicine information (CMI) leaflet for Azilect (rasagiline).
The CMI will tell you:
- who should not use the medicine
- which other medicines should be avoided
- how to take the medicine
- most of the possible side effects
- the ingredients.

You can get the CMI leaflet for Azilect from:
- your doctor or pharmacist
- the NPS website (nps.org.au)
- Lundbeck Australia, the Australian suppliers of Azilect (rasagiline), on (02) 8669 1000.

Information over the phone
NPS works with healthdirect Australia to provide consumers with information on medicines.

To get information about rasagiline call the NPS Medicines Line on 1300 MEDICINE (1300 633 424).
This service is available from anywhere in Australia for the cost of a local call (excluding mobiles),
Monday–Friday, 9am–5pm EST except NSW public holidays.

To report a side effect with rasagiline
Call the Adverse Medicine Event (AME) Line on 1300 134 237 (Monday–Friday, 9am–5pm EST).

The AME Line is a service where you can report possible side effects of your medicine and contribute
to national medicine safety efforts. Information on medicine-related side effects is passed on to the
Therapeutic Goods Administration (TGA) for assessment, but your personal details will remain
confidential and your privacy maintained.

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www.nps.org.au/consumers

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