

Not known: frequency cannot be estimated from the available data

- Elevated blood pressure
- Excessive drowsiness
- Sudden onset of sleep

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at Website:www.mhra.gov.uk/ yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rasagiline Brown & Burk

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 carton or blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

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.

6. Contents of the pack and other information

What Rasagiline Brown & Burk contain

- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as tartrate).
- The other ingredients are microcrystalline cellulose, maize starch 5%, pregelatinized starch, citric acid monohydrate, colloidal silicon dioxide, talc and stearic acid.

What Rasagiline Brown & Burk looks like and contents of the pack

Rasagiline Brown & Burk are presented as white to off white, circular, flat faced beveled edge, uncoated tablets, with "1" debossed on one face and plain on other face, approximately 8 mm diameter.

Pack contents are 7, 10, 14, 28, 30, 100 and 112 tablets in Alu-Alu blisters or Alu-PVC film coated with Aclar blisters.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Brown & Burk UK Limited,
5 Marryat Close,
Hounslow,
TW4 5DQ,
United Kingdom

Manufacturer

Brown & Burk UK Limited,
5 Marryat Close,
Hounslow,
TW4 5DQ,
United Kingdom.

This medicinal product is authorized in the Member States of the EEA under the following names:

Rasagiline Brown & Burk 1mg Tablets
Date of approval of the record.

This leaflet was last revised in 01/2018



BROWN & BURK

Package leaflet: Information for the User

Rasagiline Brown & Burk 1mg Tablets Rasagiline

Read all of this leaflet carefully before you starts taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rasagiline Brown & Burk is and what it is used for
2. What you need to know before you take Rasagiline Brown & Burk
3. How to take Rasagiline Brown & Burk
4. Possible side effects
5. How to store Rasagiline Brown & Burk
6. Contents of the pack and other information

1. What Rasagiline Brown & Burk is and what it is used for

Rasagiline Brown & Burk contains the active substance rasagiline and it is used for the treatment of Parkinson's disease in adults. It can be used together with or without Levodopa (another medicine that is used to treat Parkinson's disease).

With Parkinson's disease, there is a loss of cells that produce dopamine in the brain. Dopamine is a chemical in the brain involved in movement control. Rasagiline Brown & Burk helps to increase and sustain levels of dopamine in the brain.

2. What you need to know before you take Rasagiline Brown & Burk

Do not take Rasagiline Brown & Burk

- If you are allergic to rasagiline or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver problems.

Do not take the following medicines while taking Rasagiline Brown & Burk:

- Monoamine oxidase (MAO) inhibitors (e.g. for treatment of depression or Parkinson's disease, or used for any other indication), including medicinal and natural products without prescription e.g. St. John's Wort.
- Pethidine (a strong pain killer).

You must wait at least 14 days after stopping Rasagiline Brown & Burk treatment and starting treatment with MAO inhibitors or pethidine.

Warnings and precautions

Talk to your doctor before taking Rasagiline Brown & Burk

- If you have any liver problems
- You should speak with your doctor about any suspicious skin changes.

Tell your doctor if you or your family/carer notices that you are developing unusual behaviours where you cannot resist the impulse, urges or cravings to carry out certain harmful or detrimental activities to yourself or others. These are called impulse control disorders. In patients taking Rasagiline Brown & Burk and/or other medicines used to treat Parkinson's disease, behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive spending, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts or feelings have been observed. Your doctor may need to adjust or stop your dose (see section 4).

Rasagiline Brown & Burk may cause drowsiness and may cause you to suddenly fall asleep during day time activities, especially if you are taking

other dopaminergic medicinal products (used for the treatment of Parkinson's disease). For further information please refer to section driving and using machines.

Children and adolescents

There is no relevant use of Rasagiline Brown & Burk in children and adolescents. Therefore, Rasagiline Brown & Burk is not recommended for use under the age of 18.

Other medicines and Rasagiline Brown & Burk:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Especially tell your doctor if you are taking any of the following medicines:

- Certain antidepressants (selective serotonin reuptake inhibitors, selective serotonin-norepinephrine reuptake inhibitors, tricyclic or tetracyclic antidepressants).
- The antibiotic ciprofloxacin used against infections.
- The cough suppressant dextromethorphan.
- Sympathomimetics such as those present in eye drops, nasal and oral decongestants and cold medicine containing ephedrine or pseudoephedrine.

The use of Rasagiline Brown & Burk together with the antidepressants containing fluoxetine or fluvoxamine should be avoided. If you are starting treatment with Rasagiline Brown & Burk, you should wait at least 5 weeks after stopping fluoxetine treatment. If you are starting treatment with fluoxetine or fluvoxamine, you should wait at least 14 days after stopping Rasagiline Brown & Burk treatment.

Tell your doctor or pharmacist if you are smoking or intend to stop smoking. Smoking could decrease the amount of Rasagiline Brown & Burk in the blood.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should avoid taking Rasagiline Brown & Burk if you are pregnant, as the effects of Rasagiline Brown & Burk on pregnancy and the unborn child are not known.

Driving and using machines

Ask your doctor for advice before you drive and operate machines, since Parkinson's disease itself as well as the treatment with Rasagiline Brown & Burk may influence your ability to do so. Rasagiline Brown & Burk can make you feel dizzy or drowsy; it can also cause episodes of sudden sleep onset.

This might be enhanced if you take other medicines to treat the symptoms of your Parkinson's disease, or if you take medicines which can make you feel drowsy, or if you drink alcohol while taking Rasagiline Brown & Burk. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking Rasagiline Brown & Burk do not drive or operate machinery (see section 2).

3. How to take Rasagiline Brown & Burk

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Rasagiline Brown & Burk is 1 tablet of 1 mg taken by mouth once daily. Rasagiline Brown & Burk may be taken with or without food.

If you take more Rasagiline Brown & Burk than you should

If you think that you may have taken too many tablets, contact your doctor or pharmacist immediately. Take the Rasagiline Brown & Burk carton/blister with you to show the doctor or pharmacist.

Symptoms reported following overdose of Rasagiline Brown & Burk included slightly euphoric mood (light form of mania), extremely high blood pressure and serotonin syndrome (see section 4).

If you forget to take Rasagiline Brown & Burk

Do not take a double dose to make up for a forgotten dose. Take the next dose normally, when it is time to take it.

If you stop taking Rasagiline Brown & Burk

Do not stop taking Rasagiline Brown & Burk without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact you doctor right away if you notice any of the following symptoms. You may need urgent medical advice or treatment:

- If you develop unusual behaviours such as compulsions, obsessive thoughts, addictive gambling, excessive shopping or spending, impulsive behaviour and an abnormally high sex drive or an increase in sexual thoughts (impulse control disorders) (see section 2).
- If you see or hear things which are not there (hallucinations).
- Any combination of hallucinations, fever, restlessness, tremor and sweating (serotonin syndrome).
- If you notice any suspicious skin changes because there is a higher risk of skin cancer (not exclusively melanoma) in patients with Parkinson's disease (see section 2).

Other side effects

Very common (may affect more than 1 in 10 people)

- Involuntary movements (dyskinesia)
- Headache

Common (may affect up to 1 in 10 people)

- Abdominal pain
- Fall
- Allergy
- Fever
- Flu (influenza)
- General feeling of being unwell (malaise)
- Neck pain
- Chest pain (angina pectoris)
- Low blood pressure when rising to a standing position with symptoms like dizziness/light-headedness (orthostatic hypotension)

- Decreased appetite
- Constipation
- Dry mouth
- Nausea and vomiting
- Flatulence
- Abnormal results of blood tests (leucopenia)
- Joint pain (arthralgia)
- Musculoskeletal pain
- Joint inflammation (arthritis)
- Numbness and muscle weakness of the hand (carpal tunnel syndrome)

- Decreased weight
- Abnormal dreams
- Difficulty in muscular coordination (balance disorder)
- Depression
- Dizziness (vertigo)
- Prolonged muscle contractions (dystonia)
- Runny nose (rhinitis)
- Irritation of the skin (dermatitis)
- Rash
- Bloodshot eyes (conjunctivitis)
- Urinary urgency

Uncommon (may affect up to 1 in 100 people)

- Stroke (cerebrovascular accident)
- Heart attack (myocardial infarction)
- Blistering rash (vesiculobullous rash)
- Confusion