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Pharmacode

Package leaflet: Information for the user

Rasagiline Ascend 1 mg Tablets

rasagiline mesilate

Read all of this leaflet carefully before you start 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 Ascend is and what it is used for
2. What you need to know before you take Rasagiline Ascend
3. How to take Rasagiline Ascend
4. Possible side effects
5. How to store Rasagiline Ascend
6. Contents of the pack and other information

1. What Rasagiline Ascend is and what it is used for

Rasagiline Ascend 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. This medicine helps to increase and sustain levels of dopamine in the brain.

2. What you need to know before you take Rasagiline Ascend

Do not take Rasagiline Ascend
- 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 Ascend:
- Monoamine oxidase (MAO) inhibitors (such as for treatment of depression or Parkinson's disease or used for any other indication), including medicinal and natural products without prescription such as St. John's Wort.
- Pethidine (a strong pain killer).

You must wait at least 14 days after stopping Rasagiline Ascend treatment and starting treatment with MAO inhibitors or pethidine

Warnings and precautions
Talk to your doctor before taking Rasagiline Ascend
- if you have any liver problems
- if you develop any suspicious skin changes. Treatment with rasagiline may possibly increase the risk of skin cancer.

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 this medicine 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).

This medicine 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 Ascend in children and adolescents. Therefore, this medicine is not recommended for use under the age of 18.

Other medicines and Rasagiline Ascend
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 Ascend together with the antidepressants containing fluoxetine or fluvoxamine should be avoided:
- If you are starting treatment with Rasagiline Ascend, 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 Ascend treatment.

Tell your doctor or pharmacist if you are smoking or intend to stop smoking. Smoking could decrease the amount of rasagiline 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 Ascend if you are pregnant, as the effects of rasagiline 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 may influence your ability to do so. This medicine 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 this medicine. If you have experienced somnolence and/or episodes of sudden sleep onset before, or while taking Rasagiline Ascend do not drive or operate machinery (see section 2).

3. How to take Rasagiline Ascend

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 Ascend is 1 tablet of 1 mg taken by mouth once daily. This medicine may be taken with or without food.

If you take more Rasagiline Ascend than you should
If you think that you may have taken too many Rasagiline Ascend tablets, contact your doctor or pharmacist immediately. Take the Rasagiline Ascend carton/ blister or bottle with you to show the doctor or pharmacist.

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

If you forget to take Rasagiline Ascend
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 Ascend
Do not stop taking this medicine without first talking to your doctor.

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

4. Possible side effects

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

Contact your 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)

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 (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/lightheadedness (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
- blood shot eyes(conjunctivitis)
- urinary urgency

Uncommon: (may affect up to 1 in 100 people)
- stroke (cerebrovascular accident)
- heart attack (myocardial infarction)
- blistering rash (vesiculobullous rash)

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 the Yellow Card Scheme at: 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 Ascend

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

This medicine does not require any special storage conditions.

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 Ascend contains
- The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as mesilate).
- The other ingredients are: microcrystalline cellulose, maize starch, colloidal Silicon Dioxide, citric Acid, monohydrate, pregelatinized Starch (maize), talc, stearic acid.

What Rasagiline Ascend looks like and contents of the pack
White to off white, uncoated round flat, beveled tablets debossed with "RAS" on one side and "I" on other side.

The tablets are available in blisters in packs of 7, 10, 28, 30, 100 and 112 tablets or in a bottle containing 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in 09/2023.

PT XXXX

Alkem Laboratories Limited			
Product: Rasagiline Tablets 1 mg		Market: Ascend, UK	Size:
Itemcode: PT XXXX	Version No: 00	Superseed No: NA	Mfg Location: Amaliya
Pantone No: Black			Pack Size: NA
Component: Insert	Style: Folded	Substrate:	
Change Part No:		Pharmacode:	Barcode: NA
Reason for Issue: New artwork			Change Control No:
Date of Initiation: 26/07/2021			Final approval of artwork:
Modification Date: 29/09/2022			