PATIENT INFORMATION LEAFLET

This leaflet tells you about **AZILECT 1 mg TABLETS**

Please read all of this leaflet carefully before taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS OF THE MEDICINAL PRODUCT:

AZILECT 1 mg is a Schedule 4 (S4), medicine.

NAME OF THE MEDICINAL PRODUCT:

The name of this medicine is **AZILECT 1 mg TABLETS**.

WHAT AZILECT TABLETS CONTAIN:

The active substance is rasagiline. Each tablet contains 1 mg rasagiline (as mesylate).

The other ingredients are mannitol, colloidal anhydrous silica, maize starch, pregelatinised maize starch, stearic acid, talc.

WHAT AZILECT IS USED FOR:

AZILECT is used for the treatment of Parkinson's disease as monotherapy (without levodopa) or as adjunct therapy (with levodopa).

In Parkinson's disease there is a loss of cells producing dopamine in certain areas in the brain. **AZILECT** enables increased and sustained levels of dopamine in these areas.

BEFORE TAKING THIS MEDICINE:

If you are taking other medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional.

Do not use AZILECT:

- If you are allergic to rasagiline mesylate or any other ingredient.
- If you have moderate to severe liver insufficiency.

Do not take monoamine oxidase (MAO) inhibitors whether used as antidepressants, for the treatment of Parkinson's disease, or for any other indication (including medicinal and natural products without prescription e.g., St. John's Wort), while taking **AZILECT.**

Do not take the strong pain killer, pethidine, while taking **AZILECT.**

You should wait at least 14 days after stopping **AZILECT** treatment and starting treatment with MAO inhibitors or pethidine.

Take special care with AZILECT:

- if you have mild liver insufficiency
- if you take medicines containing fluoxetine, fluvoxamine, dextromethorphan or sympathomimetics, please see section "Taking other medicines"

AZILECT is not recommended for use in patients under the age of 18.

Pregnancy and breastfeeding

If you are pregnant or planning to become pregnant or are breast feeding, please consult your doctor, pharmacist or other healthcare professional for advice before taking AZILECT.

Taking other medicines with AZILECT:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AZILECT** with these medicines may cause undesirable interactions. Please consult your medical doctor, pharmacist, or other healthcare professional for advice.

The following medicines require specific medical advice before being taken together with **AZILECT**: Certain antidepressants (selective serotonin reuptake inhibitors, tricyclic, or tetracyclic antidepressants), the antibiotic ciprofloxacin used against infections, the cough suppressant dextromethorphan, sympathomimetics such as those present in nasal and oral decongestants and cold medications containing ephedrine or pseudoephedrine.

The use of **AZILECT** together with the antidepressants containing fluoxetine or fluvoxamine should be avoided. You should wait at least five weeks after stopping fluoxetine treatment and starting treatment with **AZILECT**. You should wait at least 14 days after stopping **AZILECT** treatment and starting treatment with fluoxetine or fluvoxamine.

HOW TO TAKE THIS MEDICINE:

Always take **AZILECT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose of **AZILECT** is one tablet of 1 mg taken orally once daily.

AZILECT may be taken with or without food.

If you take more AZILECT than you should:

If you think that you may have taken too many **AZILECT** tablets, contact your doctor or pharmacist immediately. Take the **AZILECT** carton/bottle with you to show the doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take AZILECT:

If you have forgotten to take a dose of **AZILECT** take the next dose at the usual time. Do not take a double dose to make up for the one you missed.

POSSIBLE SIDE EFFECTS:

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.

Very common (more than 10% of the patients):

Abnormal movements (dyskinesia), headache.

Common (between 1-10% of the patients):

Stomach pain, accidental injury (primary falls), allergic reaction, fever, flu syndrome, generally feeling unwell (malaise), neck pain, chest pain (angina pectoris), low blood pressure when rising to a standing position (postural hypotension), loss of appetite, constipation, indigestion, dry mouth, vomiting, abnormal results of blood tests (leucopenia), joint pain (arthralgia), arthritis, tenderness and swelling of tendons (tenosynovitis), weight loss, abnormal dreams, difficulty in muscular co-ordination (ataxia), depression, dizziness, prolonged muscle contractions (dystonia), runny nose (rhinitis), contact dermatitis, rash, vesiculobullous rash, conjunctivitis, urinary urgency.

Uncommon (between 0.1-1% of the patients):

Stroke (cerebrovascular accident), heart attack (myocardial infarct).

In addition, skin cancer was reported in around 1% of patients in the placebo controlled clinical trials. Nevertheless, scientific evidence suggests that Parkinson's disease, and not any medicine in particular, is associated with a higher risk of skin cancer (not exclusively melanoma). You should speak with your doctor about any suspicious skin changes.

In post marketing experience symptoms of hallucinations and confusion have been observed in Parkinson's disease patients treated with **AZILECT.**

STORAGE INSTRUCTIONS:

Store at or below 25 °C in the original package.

Blisters: Do not remove blisters from outer carton until required for use.

Bottles: Keep well closed.

Do not use after the expiry date shown on the carton, blister or bottle.

STORE ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION:

Blisters: Aluminium/aluminium blister packs of 7, 10, 28, 30, 100 and 112 tablets. The following information appears on the blister pack: Azilect ® 1 mg tablets; rasagiline; Lundbeck; batch number and expiry date.

Bottles: White, high-density polyethylene bottle with a standard non child-resistant cap or with a child-resistant cap, containing 30 tablets.

Not all pack sizes may be marketed.

IDENTIFICATION:

White to off-white, round, flat, bevelled tablet; debossed "GIL 1" on one side and plain on the other side.

REGISTRATION NUMBER:

41/5.4.1/0781

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