PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only.

AZILECT® Tablets

Tablets

Composition

Each tablet contains:

Rasagiline (as mesilate) 1 mg

For the list of inactive ingredients in the preparation, see section 6 – "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

AZILECT is intended for the treatment of Parkinson's in adults, and can be used with or without taking levodopa.

Therapeutic group:

Selective monoamine oxidase type B inhibitors.

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

2. BEFORE USING THE MEDICINE

☒ Do not use the preparation if:

- You are sensitive (allergic) to the active ingredient (rasagiline) or any of the additional ingredients contained in the medicine (see section 6 – "Further information").
- You are suffering from severe liver insufficiency.

Do not use AZILECT concomitantly with the following medicines:

- Pethidine (a strong pain killer).
- Monoamine oxidase inhibitors (whether given as medicines for depression, Parkinson's disease, or any other indication, including natural or medicinal preparations given without a doctor's prescription, e.g. St. John's Wort for depression).

You must wait at least 14 days between discontinuing AZILECT and starting treatment with monoamine oxidase inhibitors or with pethidine.

Special warnings regarding use of the medicine

Before beginning treatment with AZILECT, tell the doctor if:

- you are suffering from a liver problem.
- if you noticed suspicious skin changes.

Notify the doctor if your family/caregiver notice that you are developing unusual behaviors, where you fail to resist an impulse, urge or desire to carry out actions harmful or destructive to yourself or others. This condition is defined as impulse control disorders. In patients taking AZILECT together with other medicines to treat Parkinson's disease, behavior disorders, such as compulsive behavior, obsessive thoughts, gambling addiction, excessive spending, impulse to behave abnormally, increased sexual drive or increased sexual thoughts/excitement have been observed. Your doctor will consider adjusting the dosage or stopping the medicine (see section 4 – "Side effects").

AZILECT may cause drowsiness and may cause you to suddenly fall asleep during day time activities, especially if you are taking other dopaminergic medicines (used to treat Parkinson's disease). For further information, see "Driving and operating machinery" section.

❗ Use in children and adolescents

The safety and effectiveness of AZILECT in children and adolescents has not been tested; the medicine has not been used to treat Parkinson's in children and adolescents. Therefore, AZILECT is not intended for use under 18 years of age.

❗ Smoking

Inform the doctor or pharmacist if you smoke or plan to stop smoking. Smoking can reduce the levels of AZILECT in the blood.

❗ If you are taking, have recently taken or plan to take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In particular, inform the doctor if you are taking the following medicines:

- Antidepressants (e.g., tricyclics, tetracyclics, selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs]), monoamine oxidase inhibitors.
- Ciprofloxacin (an antibiotic against infections).
- Dextromethorphan (cough suppressant).
- Sympathomimetics such as those present in eye drops, oral or nasal decongestants or cold medicines that contain ephedrine or pseudoephedrine.
- Pethidine – see in section 2 "Do not use the preparation".

Avoid using this medicine concomitantly with antidepressants that contain fluoxetine or fluvoxamine. Wait at least a period of 5 weeks between discontinuing treatment with fluoxetine and starting treatment with AZILECT. On the other hand, if you start treatment with fluoxetine or fluvoxamine, do so at least 14 days after discontinuing treatment with AZILECT.

❗ Pregnancy and breastfeeding

If you are pregnant or breastfeeding, suspect that you are pregnant or are considering becoming pregnant, consult a doctor or pharmacist before using the medicine.

You must avoid taking AZILECT if you are pregnant, as the effects of AZILECT on pregnancy and on the fetus are unknown.

❗ Driving and operating machinery

Consult with your doctor before you drive and operate machinery, since Parkinson's disease itself, as well as the treatment with AZILECT, may influence your ability to do so. AZILECT can cause dizziness or drowsiness and can also cause episodes of sudden sleep onset.

The effect can be increased 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 AZILECT.

If you have experienced drowsiness and/or episodes of sudden sleep onset in the past or while taking AZILECT, do not drive or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally: one 1 mg tablet per day, with or without food.

Use this medicine at specified time intervals, as determined by the attending doctor.

Do not exceed the recommended dosage

Do not crush/halve/chew! Swallow the tablet whole, with water.

If you accidentally take a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

An AZILECT overdose can manifest in the following symptoms: slightly euphoric mood (light form of mania), very high blood pressure and serotonin syndrome (see section 4 – "Side effects").

If you forgot to take this medicine at the required time, do not take two doses together to compensate for the forgotten dose. Take the next dose at the usual time.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with AZILECT without consulting the doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Contact the doctor immediately if:

- you develop unusual behaviors such as compulsive behavior, obsessive thoughts, gambling addiction, excessive shopping or spending, impulsive behavior and an abnormally high sex drive or an increase in sexual thoughts (impulse control disorders) (see section 2 – "Before using the medicine").
- you see or hear things that do not exist (hallucinations).
- any combination of hallucinations, fever, restlessness, tremor or sweating (serotonin syndrome).
- you notice any suspicious skin changes – consult a specialist since there is a higher risk of skin cancer (not exclusively melanoma) in patients with Parkinson's disease (see section 2 – "Before using the medicine").

Additional side effects

Very common side effects – effects that occur in more than 1 user in 10:

- involuntary movements (dyskinesia)
- headache

Common side effects – effects that occur in 1-10 in 100 users:

- abdominal pain
- falling
- allergic reactions
- fever
- flu
- general unwell feeling
- neck pain
- chest pain (angina pectoris)
- low blood pressure upon transitioning from sitting to standing with symptoms such as dizziness
- anorexia (lack of appetite)
- constipation
- dry mouth
- nausea and vomiting
- abdominal bloating
- abnormal blood test results (leucopenia - reduced number of white blood cells)
- joint pain
- muscle pain
- arthritis
- numbness and weakness of the hand muscles (Carpal Tunnel syndrome)
- weight loss
- abnormal dreams
- difficulty with muscle coordination (balance disturbance)
- depression
- dizziness (vertigo)
- prolonged muscle contractions (dystonia)
- runny nose (nasal inflammation)
- skin irritation (skin inflammation - dermatitis)
- rash
- red and swollen eyes (conjunctivitis)
- urinary urgency

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- stroke
- heart attack (myocardial infarction)
- a rash that appears in the form of blisters

Side effects whose frequency is unknown (it is not possible to know the frequency based on the existing data)

- rise in blood pressure
- excessive drowsiness
- sudden onset of sleep

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C. Store in the original package.
- Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Mannitol, starch, pregelatinized starch, stearic acid, talc, colloidal silicon dioxide.

What the medicine looks like and the contents of the package

A white to off-white, round tablet, debossed with "GIL" and "1" underneath on one side and plain on the other side.

The package contains 10 or 30 tablets.

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address

Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health in June 2014 and was updated in February 2018 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

132.17.31000