

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) – 1986**  
**The medicine is dispensed with a doctor's prescription only**

**Name of the medicine, form and strength**

**Selgin 5 mg tablets**

**Composition:**

**Each tablet contains:** Selegiline Hydrochloride 5 mg

Inactive ingredients and allergens (see section 6)

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. 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?**

Treatment of Parkinson's disease or its symptoms.

**Therapeutic class:** Monoamine oxidase-B inhibitors.

**2. Before using the medicine**

**❗ Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or any of the other ingredients of the medicine (for a list of inactive ingredients, see section 6).
- You are taking pethidine or any other opioid analgesic such as codeine, tramadol or buprenorphine.
- You are taking antidepressants (see Drug interactions). Antidepressants should be discontinued several weeks before starting Selgin.
- You are taking any monoamine oxidase inhibitors, such as the antibiotic linezolid.
- You are taking any medicines for treatment of migraines, e.g. sumatriptan, naratriptan, zolmitriptan, rizatriptan.
- You are taking sympathomimetic medicines, such as medicines for asthma or for relief of nasal congestion.
- You are suffering from stomach or duodenal ulcers.
- You are suffering from a movement or muscle disorder that is unrelated to Parkinson's disease.

**❗ Taking Selgin with levodopa**

Selgin should not be used together with levodopa if you have any of the following conditions:

- Heart or blood vessels problems (cardiovascular disease).
- Chest pain (angina pectoris).
- High blood pressure.
- Fast or irregular heartbeats (e.g., tachycardia or arrhythmia).
- Overactive thyroid.
- Narrow-angle glaucoma.
- A tumor of the adrenal gland (pheochromocytoma) or the prostate (prostate adenoma).

- Serious mental problems (e.g., schizophrenia or advanced dementia).

**❗ Special warnings regarding the use of the medicine**

Before starting treatment with Selgin, inform your doctor if:

- You are suffering from uncontrolled high blood pressure, angina pectoris, strong heartbeats, arrhythmia.
- You are suffering from kidney or liver problems.
- You are suffering from a mental illness, anxiety or sleeping problems.
- You have a history of stomach ulcers.
- You are taking a medicine called levodopa, which may cause agitation and uncontrollable movements. You may require frequent medical monitoring, and your doctor may adjust your dosage of selegiline.
- You are about to undergo surgery. Selgin may interfere with certain agents used for general anesthesia.
- You have a history of uncontrollable impulses or behaviors (e.g., gambling, excessive sexual behavior) (see section 4 - Side effects).

Using a buprenorphine preparation together with Selgin may lead to serotonin syndrome, a potentially life-threatening condition (see "Drug interactions").

**❗ Children and adolescents**

This medicine is not intended for children, since it has not been tested in children.

**❗ Drug interactions**

**If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist.** Especially if you are taking:

- Amantadine, dopamine or levodopa (for treatment of Parkinson's disease).
- Antidepressants, such as: citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline, protriptyline. These medicines should not be taken together with Selgin.
- Pethidine or any other opioid analgesic such as codeine, tramadol or buprenorphine. These medicines should not be taken together with Selgin. These medicines may interact with Selgin and cause symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Consult your doctor if you experience these symptoms.
- Linezolid - antibiotic. This medicine should not be taken together with Selgin.
- Sympathomimetic medicines such as medicines for asthma or for relief of nasal congestion. These medicines should not be taken together with Selgin.
- Medicines for treatment of migraines, e.g. sumatriptan, naratriptan, zolmitriptan, rizatriptan. These medicines should not be taken together with Selgin.

- Medicines for treatment of high or low blood pressure.
- Medicines for mood and for treatment of mental illnesses.
- Anti-anxiety medicines, medicines for sleeping disorders or for relaxation of gut muscles (medicines that act on the central nervous system).
- Medicines for anesthesia.
- Medicines for treatment of heart problems (e.g., digitalis) - you may require frequent medical monitoring.
- Blood thinners (anticoagulants) - you may require frequent medical monitoring.
- Medicines used for hormone replacement therapy (HRT).
- Altretamine - for treatment of ovarian cancer.
- Oral contraceptives (consult your doctor regarding other types of contraceptives).

Selgin requires a certain period of time to be completely removed from the body, before starting certain other medicines. If you intend to start another medicinal treatment, consult with your doctor.

**❗ Use of the medicine and food**

Selgin may be taken with food and drink.

Your doctor may recommend that you avoid certain foods containing tyramine such as cheese, broad beans, Bovril, yeast extracts or fermented soya bean products.

**❗ Use of the medicine and alcohol consumption**

Alcohol should be avoided while taking Selgin.

**❗ Pregnancy, breastfeeding and fertility**

Do not use Selgin if you are pregnant, think you may be pregnant or are planning to become pregnant.

Do not use Selgin if you are breastfeeding.

Consult with your doctor or pharmacist before using the medicine.

No information is available regarding effects on fertility.

**❗ Driving and operating machinery**

Avoid driving or operating dangerous machinery while using the medicine if you are suffering from dizziness, drowsiness and/or slow responsiveness.

Selgin may cause a sensation of dizziness or drowsiness. Do not drive while using this medicine until you know how it affects you.

**❗ Important information about some ingredients of the medicine**

Selgin contains lactose. If you have been told by a doctor that you have an intolerance to some sugars, consult your doctor before taking this medicine.

**3. How should you use the medicine?**

Always use Selgin according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. **Do not exceed the recommended dose.**

Regular dosage when no other order from the doctor is given: For adults and children over 12 years of age - one tablet

in the morning and one tablet at noon, or two tablets in the morning.

Do not exceed the recommended dose.

This medicine is usually not intended for children.

This medicine should be used at set intervals as determined by the treating doctor.

**Method of administration:**

Swallow the medicine with a little water.

**Crushing/halving/chewing:**

If necessary, the tablet may be crushed.

**If you accidentally took a higher dose** or if a child or someone else accidentally swallowed the medicine, contact a doctor immediately or proceed to a hospital emergency room and bring the package of the medicine with you.

Overdose symptoms include agitation, restlessness, tiredness, severe headache, tremor, high or low blood pressure, breathing difficulties, shortness of breath, hallucinations, dizziness, fast irregular heartbeat, chest pains, severe muscle spasms, fever, excessive sweating, loss of consciousness and fits.

**If you forgot to take this medicine** at the appointed time, take your dose as soon as you remember. If you only remember in the late afternoon or in the evening, skip the forgotten dose. Never take two doses together.

Follow the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

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

**If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.**

**4. Side effects**

As with any medicine, using Selgin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

**Very common side effects - affecting more than 1 patient out of 10:**

- Sore mouth and swollen gums (stomatitis)
- Common side effects - affecting 1-10 patients out of 100:**
- Difficulty controlling your movements and loss of balance, falls
- Slow heart rate (bradycardia)
- Dizziness, fainting, headache, tremor
- Sleep disturbances, confusion, hallucinations
- Depression
- High or low blood pressure
- Abnormal liver tests due to liver enzymes elevation
- Nausea, constipation, diarrhea, mouth ulcers
- Stuffy nose, sore throat
- Back pain, joint pain (arthralgia), muscle cramps
- Tiredness

- Sensation of dizziness (vertigo)
- Excessive sweating
- Uncommon side effects - affecting 1-10 patients out of 1,000:**
- Chest pain (angina pectoris), nervousness, swelling of the ankles
- Fast, irregular, unstable heart rate (palpitations)
- Sleeping problems, strange dreams, anxiety or irritability, mood swings, psychosis
- Shortness of breath (dyspnea)
- Blurry vision

- Lowering of blood pressure, which may lead to a feeling of light-headedness, particularly when standing up
- Problems starting, passing and stopping urination, or altered frequency of urination
- Impaired liver function due to liver enzymes elevation (transient rise of ALAT enzyme levels)
- Muscle weakness (myopathy)
- Decrease in white blood cells (leukocytopenia) and platelets (thrombocytopenia) which may increase the risk of bleeding, bruising or infections
- Loss of appetite
- Sore throat (pharyngitis), dry mouth
- Hair loss, blisters or spots on skin.

**Rare side effects - affecting 1-10 patients out of 10,000:**

- Lowering of blood pressure, which may lead to a feeling of light-headedness, dizziness or fainting, particularly when standing up
- Skin reactions

**Side effects whose frequency is unknown (frequency cannot be estimated from the available data), however these side effects can be considered to be very rare:**

- Hypersexuality (altered sexual activity and behavior of significant concern to the patient or to others)
- Unusual urges and/or behaviors (such as excessive gambling or other behaviors)
- Inability or difficulty passing urine

**Side effects that occur when Selgin is taken with levodopa:**

**Taking Selgin with levodopa may increase the side effects of levodopa, e.g.:**

- Excessive and uncontrollable movements after taking your medicine
- Confusion, hallucinations, sleeping problems, nervousness, restlessness
- Palpitations, irregular, unstable heart rate, chest pain, swollen ankles and shortness of breath
- Nausea, dizziness, feeling faint, dry mouth, loss of appetite, problems passing urine
- Lowering of blood pressure, which may lead to a feeling of light-headedness or fainting, particularly when standing up
- Hypersexuality (altered sexual activity and behavior of significant concern to the patient or to others)

- Decrease in white blood cells (leukocytopenia) and platelets (thrombocytopenia) which may increase the risk of bleeding, bruising or infections and temporary liver problems
- Headache, skin reactions, hair loss

These side effects usually subside when the dosage of levodopa is reduced. If you experience any of the above side effects, consult your doctor about reducing the dosage.

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

Side effects may be reported to the Ministry of Health by clicking on the link “report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

**5. How to store the medicine?**

**Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor. Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.

**Storage:** Store at a temperature lower than 25°C. Store in the original packaging to protect from light and moisture.

**6. Additional information**

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

Lactose, maize starch, crospovidone, povidone, hydrogenated vegetable oil, colloidal silicone dioxide.

What does the medicine look like and what are the contents of the package:

Each tablet of Selgin is a round, yellowish-white tablet. Each package contains 1, 2, 5, 6, 10, 20, 50, 100 blister trays which contain 10 tablets each.

Not all package sizes may be marketed.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 069272827800  
Manufacturer and license holder: CTS Chemical Industries Ltd., Kiryat Malachi, P.O. Box 385.

This leaflet was revised in May 2021 in accordance with the Ministry of Health guidelines.