

Package leaflet: Information for the patient**Nicergolină Slavia 30 mg film-coated tablets**
Nicergoline

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

- Keep this leaflet. You may need to read it again.
- Ask your physician, your pharmacist or nurse if you need additional information.
- This medicine has been prescribed only for you. You should not give it to other people. It can harm them, even if they present the same disease symptoms as you.
- If you get any side effects, talk to your physician, your pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nicergolină Slavia is and what it is used for
2. What you need to know before you use Nicergolină Slavia
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1. What Nicergolină Slavia is and what it is used for

Nicergolină Slavia belongs to a group of medicines called ergot alkaloids.
The medicine improves brain function and acts as an antioxidant of brain cells.

Nicergolină Slavia is indicated as an adjuvant in:

- symptomatic treatment of diseases characterized by deterioration of cognitive function associated with vascular dementia (multi-infarct dementia), degenerative diseases associated with dementia (senile and presenile dementia of the Alzheimer's type, Parkinson's dementia). The medicinal product also has favorable effects on behavioral and mood disorders. The medicine favorably influences the ability to be alert, the function of concentration and the emotional state. By improving daily activity, the patient regains self-confidence and improves his communication with his surroundings.
- cerebral vascular and metabolic disorders occurring in the case of thrombotic cerebral vascular accidents;

- recovery therapy in patients with hemiplegia (a condition in which one side of the body is paralyzed);
- treatment of cochleo-vestibular disorders.

2. What you need to know before you use Nicergolină Slavia

Do not take Nicergolină Slavia

- if you are hypersensitive to nicergoline, other ergot alkaloids or to any of the other components of this medicine (listed in section 6);
- if you have had a recent myocardial infarction;
- if you have acute hemorrhages, brain tumors associated with increased intracranial pressure syndrome; marked decrease in heart rate (< 50 beats per minute), low orthostatic blood pressure.

Warnings and precautions

Talk to your doctor:

- if you have kidney diseases. You may need a different dosage;
- you present hemorrhagic manifestations or organic lesions with potential for bleeding, such as active gastric and duodenal ulcer, acute hemorrhagic stroke;
- you suffer from high blood pressure/low blood pressure;
- you suffer from hyperuricemia (increased concentrations of uric acid in the blood) or you have suffered from gout; • you are or intend to become pregnant;
- you suffer from fibrosis (a condition caused by excessive formation of connective tissue that can harm various organs and parts of the body);
- you experience nausea, vomiting, diarrhea, abdominal pain, cramps, a feeling of numbness and tingling in the extremities, headaches and/or a change in skin color (you become pale).

Nicergolină Slavia and other medicines

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

Nicergoline must be administered with caution in the case of concomitant treatment with:

- antihypertensive medicines (medicines that lower blood pressure) because Nicergolină Slavia may increase their effect;
- medicines metabolized by the CYP 2D6 isoenzyme: since nicergoline is metabolized by the CYP 2D6 isoenzyme, possible interactions with other medicines metabolized by the same isoenzyme must be considered;
- anticoagulant and antiplatelet medicines (blood-thinning medicines) because nicergoline inhibits platelet aggregation and reduces blood viscosity; bleeding time may be prolonged. Frequent monitoring of bleeding time is recommended.
- medicines that may influence uric acid metabolism because nicergoline may affect the metabolism and excretion of uric acid, leading to increased concentrations of uric acid in the blood;
- medicines that act on the nervous system: dose adjustments are required.

Nicergolină Slavia with food and drink and alcohol

Take Nicergolină Slavia before meals, preferably before breakfast, with a sufficient amount of liquid and without chewing the tablet. If a single daily dose is prescribed, it is recommended to take it in the morning, before breakfast.

Pregnancy and 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.

Pregnancy

Nicergolină Slavia should only be used if indicated by your doctor.

Breast-feeding

It is not known whether nicergoline is excreted in breast milk. A decision must be made either to discontinue breastfeeding or to discontinue treatment with Nicergolină Slavia, taking into account the potential risk of breastfeeding for the child and the benefit of the treatment for the woman.

Driving vehicles and using machines

Nicergolină Slavia may affect your ability to react, interfering with activities such as driving vehicles and operating machinery. Do not drive vehicles or use machinery if you experience dizziness or confusion.

Nicergolină Slavia conține glucoză

Patients with the rare glucose-galactose malabsorption syndrome should not use this medication.

Nicergolină Slavia 30 mg conține Roșu coșenilă A (E 124)

This component of the medication may cause allergic reactions.

3. How to use Nicergolină Slavia

Always use this medicine exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you are not sure.

The medicine is intended for adults. It is administered orally.

The recommended daily dose for adults is 30 mg. Temporarily, the daily dose may be increased to 60 mg.

In the case of inner ear conditions, 15–30 mg/day is recommended.

It is recommended to take the tablets in the morning and before a main meal. The tablets should be taken whole, without chewing, with a sufficient amount of liquid. If a single dose is prescribed, it is preferable to take it at breakfast.

Use in the elderly: dose adjustment of Nicergolină Slavia is not necessary.

Use in children: administration of Nicergolină Slavia is not recommended for children.

Use in patients with kidney disorders: doses should be reduced in case of renal insufficiency (*serum creatinine > 2%*).

You may need a lower dose, which will be prescribed by your doctor.

The effect of the treatment develops gradually. Since the treatment usually lasts for long periods, periodic medical check-ups are necessary at appropriate intervals, but at least once every 6 months, with the doctor assessing the appropriateness of continuing the treatment.

If you feel that the effect of Nicergolină Slavia is too weak or too strong, consult your doctor or pharmacist.

If you take more Nicergolină Slavia than you should

If you have taken more Nicergolină Slavia tablets than prescribed, consult your doctor or go to the nearest hospital.

Symptoms of overdose include cardiovascular symptoms – a pronounced, temporary drop in blood pressure and bradycardia (slowing of the heart rate). The severity of adverse reactions may vary from one patient to another.

If you forget to take Nicergolină Slavia

If you forget to take a Nicergolină Slavia tablet on time, take it as soon as you remember. However, if it is time for the next dose, skip the missed dose and return to your regular dosing schedule.

Do not take a double dose to make up for the missed one.

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

4. Possible adverse reactions

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

The following adverse reactions have been reported with the administration of nicergoline:

Common side effects (may affect up to 1 in 10 people):

- stomach discomfort.

Uncommon side effects (may affect up to 1 in 100 people):

- agitation;
- confusion;
- sleep disturbances;
- drowsiness;
- dizziness;
- headaches;
- low blood pressure;
- facial flushing;
- diarrhea;
- nausea;
- constipation;
- itching;
- increased blood uric acid levels.

Rare side effects (may affect up to 1 in 1,000 people):

- sensation of warmth;
- transient skin rash;
- fibrosis.

In addition, the following adverse reactions have been reported with the administration of ergot derivatives:

- Isolated interstitial lung disease or with pleural involvement, isolated pleural involvement (a form of lung condition characterized by scarring of the lungs or the membrane surrounding them), pulmonary fibrosis (a condition caused by excessive formation of connective tissue that can damage various organs or parts of the body).

Adverse reactions reporting

If you manifest any adverse reaction, address your doctor or pharmacist. Those can be any adverse reactions not mentioned in this package leaflet. Also, you can report the adverse reactions directly through the national reporting system, that has the details published on the National Agency of Medicines and Medical Devices of Romania, <http://www.anm.ro/>.

By reporting the adverse reactions, you can contribute in providing the additional information regarding this medicine's safety.

5. How to store Nicergolină Slavia

Keep this medicine in the sight and reach of children.

Store below 25°C, in the original package.

Do not use this medicine after the expiry date written on the box after EXP. The expiry date refers to the last day of the respective month.

EXPIRED AND/OR UNUSED MEDICATIONS MUST BE RETURNED TO PUBLIC OR PRIVATE HOSPITALS.

Do not dispose of any medicines via waste water or household waste. Ask the pharmacist how to dispose of the medicines you no longer require. These measures will help protect the environment.

6. Package content and other information

What does Nicergolină Slavia contains

Nicergolină Slavia 30 mg

- The active substance is *nicergoline*. One film-coated tablet contains nicergoline 30 mg.
- The other components are: core - microcrystalline cellulose, corn starch, povidone, talc, anhydrous colloidal silicon dioxide, magnesium stearate; film - sodium carboxymethylcellulose, maltodextrin/dextrin, glucose monohydrate, soy lecithin, titanium dioxide (E 171), yellow iron oxide (E 172), cochineal red A (E 124).

What Nicergolină Slavia looks like and package contents

Nicergolină Slavia 30 mg film-coated tablets are presented as round, biconvex, reddish-brown film-coated tablets.

Nicergolină Slavia 30 mg film-coated tablets

The medicine is packaged in boxes containing 3 and 150 blisters respectively, each with 10 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Slavia Pharm SRL
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This package information leaflet was revised in January 2025.