

PACKAGE LEAFLET: INFORMATION FOR THE USER

ADAVIN

10 mg Film-coated tablets

NICERGOLINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Adavin is and what it is used for
2. Before you take Adavin
3. How to take Adavin
4. Possible side effects
5. How to store Adavin
6. Further information

1. WHAT ADAVIN IS AND WHAT IS IT USED FOR

Adavin is a medicinal product that increases the blood flow. The increase is primarily manifested in the central nervous system and cardiovascular system. Adavin speeds up the metabolic activity of the brain cells, lowers vascular resistance and prevents the formation of platelet clots.

Adavin is intended for additional treatment of reduced mental abilities in elderly (e.g., concentration, memory impairment and orientation).

2. BEFORE YOU TAKE ADAVIN

Tell your doctor if you have any chronic illness, metabolic disorder, or an allergic reaction.

Do not take Adavin

- If you are allergic (hypersensitive) to nicergoline or any of the other ingredients of this medicine (stated in Section 6. Further information)
- If you recently had myocardial infarction

- if you experience extensive bleeding,
- if you have very slow heart rate,
- if you faint easily,
- if you suffer from postural hypotension (dizziness or fainting after getting up caused by lowering of blood pressure),
- If you are taking the sympathomimetics (medicines that are usually used to treat asthma, heart disease and eye problems) (see section "Taking other medicines")
- If you are pregnant or breast- feeding.

Take special care with Adavin

Talk with your doctor or pharmacist before using Adavin.

Pay special attention to the following facts:

- If you are taking medicines for lowering blood pressure, alert your doctor so he/she can adjust your dose
- If you have gout or if you are taking medicine for the treatment of gout, a doctor will advise you not to take Adavin (see sections "Taking other medicines" and "Possible side effects")
- If you have reduced liver function or kidney disease, or if you have a slow heart rate (bradycardia), contact your doctor
- If you have ever had, or if you have scars of connective tissue (i.e. the fibrin reaction) on the heart, lungs or abdomen, contact your doctor. If you are being treated with nicergoline for a longer period, before starting the treatment, your doctor will check the function of the heart, lungs and kidneys. If the scars appear, treatment with Adavin will be discontinued.
- If you experience tingling and burning sensation in the extremities, swelling of the legs, itching, pain in the muscles of the leg, arm and neck, loss of strength in your legs or cold, pale or bluish fingers, stop using the medicine and visit your doctor. These changes can be a sign of Ergotism (chronic poisoning with ergot alkaloids), which can occur after a long period of taking nicergoline.
- If you are an older patient, because of the increased risk of occurrence of side effects.

Safety and efficacy of the use of nicergoline in children have not been determined.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Concomitant use of nicergoline and other medicines for lowering blood pressure (antihypertensives) can increase its unwanted effects (drop in blood pressure, nausea and fatigue). Effects of sympathomimetics (see section "do not take Adavin") can be reduced by concomitant use with this medicine. Nicergoline increases the effects of beta-blockers (medicine to regulate heart rhythm) on the heart.

Concomitant use of medicines which reduce the metabolism of uric acid salts or their elimination (eg, allopurinol) may stimulate gout attack (see the sections "Take special care with Adavina" and "Possible side effects").

If you are taking medicines that have the effect on blood clotting, more frequent control of blood coagulation is required.

Taking Adavin with food and drink

This medicine should be taken before meal. In the case of digestive disorders, you can take it with food.

Pregnancy and breastfeeding

If you are pregnant or breast- feeding, if you think you might be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before using this medicine. If you are pregnant or breast- feeding you should not use nicergoline.

Driving and using machines

In sensitive persons, this medicine can cause a decrease in blood pressure and dizziness. In such cases, patients should not drive or operate machinery. Effects on the ability to drive or use machines are also increased when this medicine is taken simultaneously with alcohol.

Important information about some of the ingredients of Adavin

Adavin tablets contain sucrose. If your doctor told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE ADAVIN

Always follow the recommendations of doctors when taking Adavin. If you are not sure, contact your doctor or pharmacist. Your doctor will determine your dosage and duration of treatment.

The usual dose is 1 to 2 film-coated tablets three times a day. Take this medicine before meal.

If you take more Adavin than you should

If you have taken a higher dose of Adavin than you should, tell your doctor or pharmacist. If a patient is unconscious, induce vomiting as soon as possible. If you experience signs of poisoning, especially problems with consciousness or chest pain, contact your doctor or the nearest hospital.

If you forget to take Adavin

If you forget to take Adavin, do not take the missed dose, but take the next dose as usual and continue with treatment. Do not take a double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Adavin rarely causes side effects when used in therapeutic doses.

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Common side effects:

- elevated levels of uric acid in the blood.

Not known:

- dizziness, light-headedness, headache, anxiety, sleep disorders, slow heart rate and low blood pressure, fatigue, nausea, abdominal pain, diarrhea, constipation, dry mouth
- problems with the lungs (cough, breathing problems, pleuropulmonary changes)
- facial redness, rashes on the skin, transient attacks of redness, excessive sweating, increased urination, hypersensitivity reactions (e.g. hives) and increased appetite.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ADAVIN

Keep out of the reach and sight of children.

Store the medicine at a temperature below 25° C, protected from light.

Shelf life: 3 years

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Adavin contains**

The active substance is nicergoline. Each film-coated tablet contains 10 mg of nicergoline.

The other substances are:

Core: microcrystalline cellulose (E460), calcium phosphate dibasic dihydrate, magnesium stearate (E572), partially substituted carmellose sodium

Coating: calcium carbonate (Ir1), hypromellose (E464), sucrose, talc (E553b), gelatin (E441), titanium dioxide (E171), Capol 600 (a mixture of waxes (E901), carnauba wax (E903), shellac (E904)).

What Adavin looks like and contents of the pack

Film-coated tablets are white, round and biconvex. Boxes with three blisters each containing 10 film-coated tablets (30 film-coated tablets) that contain nicergoline 10 mg.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Lek farmacevtska družba d.d. Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

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