

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vazonat® 250 mg Capsules Meldonium

Read all of this leaflet carefully before you start taking using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Vazonat is and what it is used for
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1. WHAT VAZONAT IS AND WHAT IT IS USED FOR

Vazonat positively affects energetic metabolism of the organism and moderately activates the central nervous system.

Under the conditions of ischemia (oxygen deficiency in tissues), Vazonat restores the energetic balance between oxygen delivery and consumption in cells, activates those metabolism processes that need less oxygen consumption for energy creation. The medicine has a vasodilating effect, improves blood delivery into tissues.

Vazonat exerts expressed cardioprotective effect under the conditions of ischemia and oxygen deficiency. Vazonat decreases stenocardia spasms' frequency (strong painful spasms in heart) in patients with stenocardia, and increases the physical activity. In case of congestive heart failure, the medicine augments myocardial contractility increases tolerability to physical load. In cases of acute and chronic ischemic cerebrovascular disturbances Vazonat ameliorates cerebral blood flow in the ischemic region, promoting redistribution of blood flow in favour of ischemic zone.

As a result of Vazonat effect on CNS the memory, concentration ability and movement coordination are improved.

Vazonat is used

- Complex therapy of cardiovascular system therapy: stable angina pectoris, chronic heart failure (NYHA I-III functional class), ischemic cardiomyopathy (uninflammatory heart muscles disease), during recovery period after cardiac infarction;
- Complex therapy of acute and chronic ischemic brain blood circulation disturbances;
- Complex therapy during recovery period after disturbances of brain blood circulation, head traumas;
- In cases of decreased performance, physical and psycho emotional overload.

2. BEFORE YOU TAKE VAZONAT

Do not take Vazonat

- if you are allergic (hypersensitive) to meldonium or any of the other ingredients of Vazonat;
- if you have hard liver and/or kidneys impairment;
- if you are pregnant or nursing mother.

Take special care with Vazonat

If you have had liver and/or kidney diseases, tell it to the doctor, because it may be necessary to monitor liver and/or kidney activity characteristics.

Vazonat is not recommended to use for children till 18 years as there is no information about the administration safety and efficacy in this age group.

Taking Vazonat with other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not use concomitantly with other medicines containing meldonium (the risk of side effects' development).

Vazonat could be combined concomitantly with other antianginal drugs, anticoagulants (drugs that affect blood circulation), antiagregants (drugs that inhibit trombocytes agglutination), antiarrhythmic drugs, cardiac glycosides, diuretics (drugs that promote the excretion of and increase the amount of urine} and drugs that improve microcirculation (blood circulation in small blood vessels).

Vazonat may intensify the actions of glyceriltrinitrate, nifedipine, beta-adrenoblockers, other hypotensive agents and peripheral vasodilators.

Pregnancy and breast-feeding

During pregnancy and breast-feeding period Vazonat is prohibited.

Driving and using machines

There are no data of unfavourable Vazonat effect on the ability to drive or use machines.

3. HOW TO TAKE VAZONAT

Always take Vazonat exactly as your doctor has told you. You should check with your doctor if you are not sure. The whole capsule should be taken with water.

The doctor determines the dose and duration of treatment.

Usual adult daily dose is 500 mg – 1000 mg. 500 mg daily dose (2 capsules) is used once a day in the morning. In view of a possible development of exciting effect 1000 mg daily dose (4 capsules) is recommended to divide in two single doses and use in the first half of the day. Therapy of cardiovascular disturbances, acute and chronic brain blood circulation disturbances continues 4-6 weeks.

The treatment course of decreased performance, physical and psycho emotional overload is 10-14 days.

If you take more Vazonat than you should

In case of overdose, blood pressure may decrease that is expressed as headache, dizziness, accelerated cardiac activity. If you have used more Vazonat than you should, immediately contact a doctor!

If you forget to take Vazonat

If a regular dose is not taken, then it should be taken as soon as possible, but not more than indicated daily dose.

Do not use a double dose to make up for a forgotten dose.

If you stop taking Vazonat

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

4. POSSIBLE SIDE EFFECTS

Side effects frequency convention:

Very common – 1 or more often than 1 patient of 10

Common – less often than 1 of 10, but more often than 1 of 100 patients

Uncommon – less often than 1 of 100, but more often than 1 of 1000 patients

Rare – less often than 1 of 1000, but more often than 1 of 10 000 patients

Very rare – less often than 1 of 10 000 patients including isolated reports.

Like all medicines, Vazonat can cause side effects, although not everybody gets them. Usually the drug has a good tolerability.

Common – headache, allergic skin reactions (skin redness, urticaria, itching), dyspeptic manifestations (nausea, feeling of hardness in stomach).

Rare – decreased blood pressure.

Very rare – tachycardia.

Eosinophilia and agitation quantity is not sufficient to determine frequency of its occurrence.

In case of allergy, the use of the drug should be discontinued and, and you should consult your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE VAZONAT

Do not store above 25 °C. Protect from moisture.

Keep out of the reach and sight of children!

Do not use Vazonat after the expiry date which is stated on the packing. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6. FURTHER INFORMATION

What Vazonat contains

The active substance is meldonium.

Each capsule contains 250 mg of meldonium dihydrate.

The other ingredients are potato starch, silica colloidal anhydrous, calcium stearate.

Composition of the capsules: gelatine, titanium dioxide

What Vazonat looks like and contents of the pack

10 capsules in blister.

2, 4 or 6 blisters (20, 40, or 60 capsules) and package leaflet in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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