

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vazomag 100 mg/ml solution for injection Meldonium

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.
- 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 Vazomag is and what it is used for
2. What you need to know before you take Vazomag
3. How to take Vazomag
4. Possible side effects
5. How to store Vazomag
6. Contents of the pack and other information

1. WHAT VAZOMAG IS AND WHAT IT IS USED FOR

Vazomag belongs to a group of medicines called other cardiac agents, anti-ischemic agent of metabolic action.

Active substance of the drug meldonium dehydrate (further in the text referred to as *meldonium*) positively affects energetic metabolism of the organism and moderately activates the central nervous system.

Under the conditions of ischemia (oxygen deficiency in tissues), Vazomag restores energetic balance between oxygen delivery and its consumption in cells, activating those metabolism processes that need less oxygen for energy creation. Meldonium dilates the blood vessels improving blood supply to the body tissues. Vazomag also exerts cardioprotective effect (heart protection) under the conditions of ischemia and oxygen deficiency. Meldonium decreases the frequency of angina pectoris attacks (chest pain) and increases physical activity. In case of heart failure the medicine improves myocardial (the heart muscle) contractility and increases tolerance of the organism to physical overload.

In cases of acute and chronic ischemic cerebrovascular disorders Vazomag optimizes cerebral blood flow redistribution in favor of ischemic areas.

Vazomag possesses CNS (central nervous system) stimulant activity. As a result Vazomag improves memory, ability to concentrate and movement coordination.

Vazomag is a medicine used in

- complex therapy of cardiovascular disorders, such as stable angina pectoris, chronic heart failure (NYHA I-III functional class), ischemic cardiomyopathy, during cardiac infarction recovery period;

- complex treatment of acute and chronic ischemic cerebrovascular disorders; complex therapy during recovery period after disorders of the cerebral circulation and head traumas.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VAZOMAG

Do not take Vazomag

- if you are allergic to meldonium or any of the other ingredients of this medicine (listed in section 6)
- if you have severe liver and/or renal impairment (liver and/or kidney problems)
- if you are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Vazomag

- if you have history of liver and/or kidney problems. Your doctor may want to monitor your liver and/or kidney function.

Children and adolescents

Vazomag is not for use in children and adolescents under 18 years of age.

Other medicines and Vazomag

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

Do not use Vazomag in combination with other medicines containing meldonium (the risk of side effects development).

Vazomag can be taken together with other antianginal drugs (used to treat angina), anticoagulants (blood thinners), antiplatelet (prevent the blood from clotting) and antiarrhythmic drugs, cardiac glycosides, diuretics (remove excess fluid from the body) and drugs that improve microcirculation (blood circulation in small blood vessels).

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

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

You should not take Vazomag while you are pregnant or breast-feeding.

Driving and using machines

No studies on the effects of Vazomag on the ability to drive and use machines have been performed.

3. HOW TO TAKE VAZOMAG®

Always take Vazomag exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will determine dose and duration of the treatment.

It is recommended to take Vazomag in the first half of a day, as it can cause agitation (feeling restless).

Complex therapy of cardiovascular disorders

500-1000 mg once daily injected intravenously (directly into a vein). It is recommended to proceed treatment using Vazomag 250 mg capsules at a dose of 500-1000 mg a day. Treatment course is 4 to 6 weeks.

Complex treatment of acute and chronic ischemic cerebrovascular disorders

500 mg once a day administered intravenously during 2 to 3 weeks. It is recommended to proceed treatment using Vazomag 250 mg capsules at a dose of 500 mg daily. Average treatment course is 6 weeks.

If you have kidney and/or liver impairment, Vazomag should be used with caution.

Vazomag should not be used in children and adolescents under 18 years of age.

If you take more Vazomag than you should

Overdose can cause low blood pressure that is expressed as headache, dizziness, quicker heartbeat. If you have used more Vazomag than you should, contact a doctor immediately.

If you forget to take Vazomag

If you forget a dose, take it as soon as you remember it. However, the dose should not exceed the indicated daily dose. Do not take a double dose to make up for the forgotten dose.

If you stop using Vazomag

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

4. POSSIBLE SIDE EFFECTS

Side effects frequency is defined using the following conventions:

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, Vazomag can cause side effects, although not everybody gets them.

Usually Vazomag is well tolerated.

Common - headache, allergic reactions (skin redness, skin rash, itching)

Rare – low blood pressure.

Very rarely – tachycardia (a quicker heartbeat).

Not known (cannot be estimated from the available data) - eosinophilia (increase in certain white blood cells), agitation (feeling restless).

In case of allergy, Vazomag should be discontinued 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 VAZOMAG

Do not store above 25 °C.

Keep out of the sight and reach of children.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Vazomag contains

The active substance is meldonium dihydrate.

1 ml solution for injection contains 100 mg of meldonium dihydrate (100 mg/ml).

5 ml solution for injection (1 ampoule) contains 500 mg of meldonium dihydrate (500 mg/5ml).

The other ingredient is water for injection.

What Vazomag looks like and contents of the pack

Transparent colourless solution in 5 ml ampoule.

10 ampoules in a transparent PVC tray and package leaflet in a carton box.

Marketing Authorisation Holder and Manufacturer

JSC Olainfarm.

5, Rupnicu St., Olaine, LV-2114, Latvia.

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