

PACKAGE LEAFLET: Information for the patient

NITROSORBIT

Tablets – 10 mg

(Isosorbide dinitrate)

Read this leaflet carefully before you start taking 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 Nitrosorbit is and what it is used for
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4. Possible side effects
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1. WHAT NITROSORBIT IS AND WHAT IT IS USED FOR

Nitrosorbit contains the active substance isosorbide dinitrate. The basic pharmacological effect of isosorbide dinitrate, as all organic nitrates, is relaxing vascular smooth muscles as a result of intracellular cyclic guanosine monophosphate production inducement. Arterioles relaxation reduces systemic vascular resistance and blood pressure.

Nitrosorbit 10 mg tablets are indicated in:

- prophylaxis and treatment of angina pectoris;
- left ventricular failure.

Your doctor may have prescribed Nitrosorbit for another purpose. Talk to your doctor if you

want to know why Nitrosorbit was prescribed to you.

2. BEFORE YOU TAKE NITROSORBIT

Do not take Nitrosorbit if you:

- are allergic to the active substance and nitrates in general or to any of the excipients of the tablets;
- have hypotensive and hypovolemic conditions;
- have hypertrophic obstructive cardiomyopathy;
- have aortic stenosis;
- have cardiac tamponade;
- have mitral stenosis;
- have severe anemia;
- have closed angle glaucoma;
- have head trauma and cerebral hemorrhage;
- take at the same time sildenafil (Viagra), because it can increase the effect of the drug in reducing blood pressure.

Take special care when taking Nitrosorbit

Use of isorbide dinitrate in patients with glaucoma should be done with caution (contraindicated in closed angle glaucoma), because it increases eye pressure.

In long lasting treatment, it may develop tolerance, and when combined with other organic nitrates, may develop cross-tolerance. To avoid the tolerance, the treatment should be interrupted at intervals.

If high dose treatment with isorbide dinitrate needs to be discontinued, it is necessary to decrease gradually the dose because the immediate interruption of the treatment can cause angina.

Patients who use organic nitrates and vasodilators or other antihypertensive drugs at the same time, must be monitored carefully for any possible additive antihypertensive effects.

The concomitant use of alcohol can cause hypotension, therefore it should be avoided.

This medicine should be used with caution in hypothyroidism, malnutrition or hypothermia.

Caution is required in hypoxemia or other ventilation and perfusion impairments.

The use of this drug should be avoided during pregnancy.

The use of this drug should be avoided during lactation.

Taking other medicines

Treatment at the same time with other medicines can affect or be affected by Nitrosorbit.

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

There are several medicines which potentiate the hypotensive effect of isosorbide dinitrate, among which:

- ACE-inhibitors;
- alpha-blockers;
- aldesleukin;
- general anesthetics;
- angiotensin II receptor antagonists;
- MAO inhibitors;
- antipsychotics (phenothiazines);
- anxiolytics and hypnotics;
- beta-blockers;
- calcium-channel blockers;
- clonidine;
- diazoxide;
- diuretics;
- levodopa;
- methyldopa;
- muscle relaxants (baclofen or tizanidine);
- alprostadil;
- sildenafil (significantly enhances the hypotensive effect, avoid concomitant use);
- tadalafil (significantly enhances the hypotensive effect, avoid concomitant use);
- vardenafil (avoid concomitant use);
- vasodilator antihypertensives (hydralazine, minoxidil, nitroprusside).

The hypotensive effect of nitrates is antagonised by NSAIDs, corticosteroids, estrogens.

Alcohol increases the hypotensive effect of isosorbide dinitrate.

Nitrates combination with dihydroergotamine can cause an increase of systolic blood pressure and of the anginal effects.

Taking Nitrosorbit with food and drinks

The use at the same time of isosorbide dinitrate and alcohol can cause hypotension and should therefore be avoided.

Pregnancy

Talk to your doctor or pharmacist if you are pregnant or are planning to become pregnant. The safety of using organic nitrates in pregnancy is not clear yet, so this drug should not be used during pregnancy.

Breastfeeding

Inform your doctor or pharmacist if you breastfeed your child. The safety of using organic nitrates in breast-feeding is not clear yet, so this drug should not be used during this period.

Driving and using machines

Due to the hypotensive effect of Nitrosorbit, even if taken in therapeutic doses, this drug can affect driving skills or working with machinery.

This effect is especially increased if alcohol is consumed at the same time.

Important information about some of the excipients of Nitrosorbit

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

3. HOW TO TAKE NITROSORBIT

Please follow the doctor's advice on the administration route and dosage of Nitrosorbit. If you feel that its effect is too strong or too weak, please contact your doctor or pharmacist.

Tablets posology is as follows:

In angina pectoris, 20 - 120 mg daily, in divided doses;

In left ventricular failure, 40-160 mg and if necessary up to 240 mg daily, in divided doses.

If you take more Nitrosorbit

If you take more Nitrosorbit than you should, or if the children take it by mistake, please contact your doctor or hospital straight away for receiving any advice on the risks or the actions to be taken.

If you forget to take Nitrosorbit

If you forget to take a dose, take the next dose at its usual time.

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

If you stop taking Nitrosorbit

If the treatment with isosorbide dinitrate needs to be discontinued, it is necessary to decrease gradually the dose because the immediate interruption of the treatment can cause angina.

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

4. POSSIBLE SIDE EFFECTS

All medicines might cause side effects. Sometimes they are serious, mostly they are not. Do not worry from this list of possible side effects. No one of them might appear to you.

Use for a long time and in high doses of this medicine may favor these effects:

- headache, especially when you start taking this medicine, which can be avoided either by lowering the dosage or using an analgesic, but the headache usually disappears with continued treatment;
- dizziness or weakness and any other sign of cerebral ischemia caused by postural hypotension;
- face redness;
- tachycardia;
- gastrointestinal disorders;
- in patients sensitive to nitrates antihypertensive effect, nausea, vomiting, asthenia, hypotension, sweating, collapse may occur, even when using the usual therapeutic doses;

- after long-term use of isosorbide dinitrate, exanthema may appear, and at higher doses methemoglobinemia.

If you get any side effects not listed in this leaflet, please contact your doctor or pharmacist.

5. HOW TO STORE NITROSORBIT

Keep out of the sight and reach of children.

Do not take Nitrosorbit after the expiry date stated on the packaging.

Store below 25°C!

6. FURTHER INFORMATION

What Nitrosorbit contains

The active substance is isosorbide dinitrate.

Each tablet contains 10 mg isosorbide dinitrate.

The excipients are: lactose monohydrate, microcrystalline cellulose, magnesium stearate, talc.

Contents of the pack

Box with 30 tablets, box with 60 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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