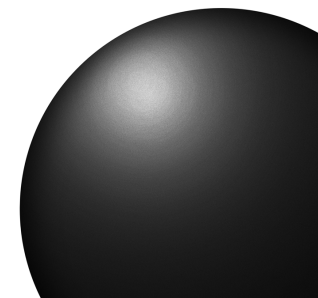


isoket® 10 mg

ISOSORBIDE DINITRATE



Patient information

Dear patient,
Please read the following user information carefully, because it contains important information on what you should consider when using this drug. Please ask your doctor or pharmacist in case of any questions.

isoket® 10 mg

Active ingredient: isosorbide dinitrate

COMPOSITION

Pharmaceutically active ingredients:

One tablet of isoket® 10 mg contains isosorbide dinitrate 10 mg.

Other ingredients:

Lactose 1 H₂O, talc, aluminium hydroxide distearate, microcrystalline cellulose, potato starch, highly disperse silicon dioxide

PRESENTATION AND CONTENTS

Packs of 60 (N2) and 100 (N3) tablets, hospital-size packs of 350 (5 x 70) and 500 tablets

Substance group/mode of action

Organic nitrates

NAME AND ADDRESS OF THE PHARMACEUTICAL MANUFACTURER

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Alfred-Nobel-Str. 10
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INDICATIONS

- Prophylaxis and long-term therapy of angina pectoris (chest pain)
- Pulmonary hypertension
- Acute myocardial infarction
- Therapy of severe myocardial insufficiency (in combination with cardiac glycosides, diuretics, ACE inhibitors, vasodilators)

CONTRAINDICATIONS

When must you not use isoket® 10 mg?

- Isoket® 10 mg must not be used in cases of
- allergy to nitrate-type drugs;
 - acute circulatory failure (shock, circulatory collapse);
 - very low blood pressure (marked hypotension: systolic blood pressure < 90 mmHg);
 - cardiogenic shock, unless a sufficiently high left ventricular end-diastolic pressure is ensured by intra-aortic counterpulsation or positive inotropic drugs.

isoket® 10 mg and phosphodiesterase type 5 inhibitors such as Viagra® must not be used concomitantly, because this may result in a severe blood pressure lowering effect.

Warning:

Isoket® 10 mg must never be used when you have taken recently Viagra® even if acute angina occurs.

In which cases do you have to consult your doctor before taking isoket® 10 mg?

The following section describes the cases in which isoket® 10 mg may be used only on

certain conditions and observing particular caution. Please ask your doctor in such cases. This section is also relevant when the factors mentioned below applied to you in the past.

Medical monitoring must be particularly careful in cases of:

- acute myocardial infarction with low filling pressures; isoket® 10 mg should be used only with care, decreasing the systolic blood pressure below 90 mmHg should be avoided;
- aortic and/or mitral stenosis;
- tendency towards orthostatic circulatory dysregulation;
- hypertrophic obstructive cardiomyopathy (myocardial disease with reduction of the cardiac cavities);
- constrictive pericarditis (constrictive inflammation of the pericardium);
- cardiac tamponade;
- diseases associated with elevated intracranial pressure (further increases in pressure have so far been seen only after the i.v. administration of high doses of glyceryl trinitrate).

What do you have to observe during pregnancy and lactation?

For reasons of particular caution, isosorbide dinitrate should be used only at a physician's special order during pregnancy and lactation. Animal experiments have not yielded any indication of fetal damage.

What has to be considered in children?

There are no reports so far concerning the treatment of children.

PRECAUTIONS OF USE AND WARNINGS

Which precautions have to be observed?

What do you have to observe when driving a motor-vehicle or operating machinery or working in unsafe places?

Even when used in accordance with the instructions, this drug can alter the reactivity such as to impair the ability required to drive a motor-vehicle, to operate machinery or to work in unsafe places. This is particularly true when the therapy is started, the dose is raised, the preparation is changed or the preparation interacts with alcohol.

INTERACTIONS WITH OTHER DRUGS

Which other drugs affect the effect of isoket® 10 mg?

The concomitant use of antihypertensives, calcium antagonists, neuroleptics, other vasodilators, beta blockers or tricyclic antidepressants, and alcohol can enhance the hypotensive effect of isoket® 10 mg.

This is true in particular for the concomitant use of phosphodiesterase type 5 inhibitors such as Viagra® (see "Contraindications").

How are the effects of other drugs affected by isoket® 10 mg?

When used together with dihydroergotamine, isoket® 10 mg may lead to an increase in the dihydroergotamine level and thus enhance the effect of the latter.

Please note that this information may also apply to drugs you took a short time ago.

DOSAGE, MODE AND DURATION OF ADMINISTRATION

The following instructions apply unless your doctor prescribed isoket® 10 mg differently. Please observe the instructions for use, because isoket® 10 mg will not take full effect otherwise.

How should you take isoket® 10 mg?

Peroral administration:

At the beginning of therapy, 1 tablet of isoket® 10 mg two to three times daily. Take the tablets without chewing and with liquid independently of meals. In cases of greater demands for nitrate, the dose can be raised to 10 mg four times daily.

Sublingual administration:

During an anginal attack, or as a prophylactic measure immediately prior to physical or mental stress liable to induce an attack, allow 1/2 tablet to dissolve under your tongue or in your cheek.

To divide a tablet, place it on a hard surface, the score on top. Pressing vertically with your thumb will halve the tablet.

Note:

Isoket® 10 mg is a low-dose drug with isosorbide dinitrate as the active ingredient. It is particularly suitable for the beginning of an Isoket therapy. Your doctor will decide on how long the therapy is to be continued. This drug is particularly suitable for the long-term therapy and should not be discontinued abruptly without consultation with your doctor.

OVERDOSAGE AND FAULTY USE

Remarks referring to overdosage, forgotten use, or notes concerning the risk of adverse consequences of discontinuation.

Please inform your doctor immediately in such cases.

SIDE EFFECTS

What side effects can appear during the use of isoket® 10 mg?

Headache ("nitrate headache") commonly occurs when the treatment begins; experience has shown it to subside in most cases after several days of regular use.

On the first use, but also when the dose is raised, a decrease in blood pressure and/or circulatory dysregulation on changes of position (orthostatic hypotension) are occasionally observed; these symptoms can be accompanied by a reflex increase in heart rate, dizziness, and feelings of vertigo and weakness.

Nausea, vomiting, temporary skin reactions (flushing), and allergic skin reactions are rare.

Infrequently a very marked general decrease in blood pressure results in such a great reduction of coronary blood flow that an exacerbation of the anginal symptoms is induced.

States of collapse, sometimes associated with low heart rate (bradycardia) and short-term loss of consciousness (syncope), are seldom seen.

Exfoliative dermatitis (inflammatory skin disease) may occur in rare cases.

A loss of drug effect (development of tolerance) as well as a loss of drug effect after therapies with other nitrate drugs (cross-tolerance towards other nitro substances) was described. A loss of drug effect (decrease in hemodynamic effects) was observed within as few as 24 hours of continuous use.

Note:

Due to a relative redistribution of blood flow into hypoventilated alveolar areas of the lungs, the use of isoket® 10 mg can result in temporary reductions of the content of oxygen in the arterial blood (hypoxemia) and may induce the diminution of myocardial perfusion (ischemia) in patients suffering from disturbed blood flow in the coronary vessels (coronary heart disease). Please inform your doctor or pharmacist of any side effects not listed in this package insert.

Which countermeasures have to be taken in case of side effects?

Please ask your doctor in such cases.

NOTES AND SHELF-LIFE INFORMATION

The expiry date of this pack is printed on the container and the folding box. Do not use the pack after this date!

Store drugs out of the reach of children!

DATE OF INFORMATION

October 1998

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists