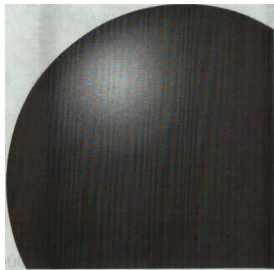


# **isoket<sup>®</sup> retard 120 mg**

ISOSORBIDE DINITRATE



Dear patient,

Please read the following patient 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.

Patient information

## **isoket<sup>®</sup> retard 120 mg**

Active ingredient: isosorbide dinitrate

### **COMPOSITION**

One prolonged-release capsule contains:

*Pharmacologically active ingredient:*

isosorbide dinitrate 120 mg

*Other ingredients:*

Lactose monohydrate, sucrose, maize starch, shellac, ethyl cellulose, talc; capsule shell: titanium dioxide (E171), iron oxide (E172), gelatin

### **PRESENTATION AND CONTENTS**

Packs of 20, 30 (N1), 60 (N2), and 100 (N3) prolonged-release capsules

### **SUBSTANCE OR INDICATION GROUP OR MODE OF ACTION**


Drug to treat blood flow disturbances in the coronary vessels of the heart

### **NAME AND ADDRESS OF THE PHARMACEUTICAL COMPANY AND THE MANUFACTURER:**

SCHWARZ PHARMA Deutschland GmbH

SCHWARZ PHARMA AG

SANOL GmbH



Alfred-Nobel-Str. 10  
D-40789 Monheim  
Phone: +49 21 73 48 48 47  
Fax: +49 21 73 48 48 41  
Internet: <http://www.schwarzpharma.com>

**MANUFACTURER:**  
SCHWARZ PHARMA AG  
Alfred-Nobel-Str. 10  
D-40789 Monheim  
Phone: +49 21 73 48 48 40  
Fax: +49 21 73 48 1608

## INDICATIONS

Preventive and long-term therapy of angina pectoris (pain in the heart due to blood flow disturbances in the coronary vessels)

## CONTRAINDICATIONS

*In which cases must you not use ISOKET® retard 120 mg?*

ISOKET® retard 120 mg must not be used in:

- hypersensitivity to the active ingredient isosorbide dinitrate, to other nitro compounds or to any of the other ingredients;
- acute circulatory failure (shock, circulatory collapse);
- cardiogenic shock (shock induced by heart failure), unless a sufficiently high pressure in the heart (left ventricular end-diastolic pressure) is ensured by appropriate measures;
- very low blood pressure (marked hypotension: systolic blood pressure less than 90 mm Hg);

During a therapy with ISOKET® retard 120 mg, no phosphodiesterase type 5 inhibitors, e.g. Viagra®, must be used, as this may result in a marked hypotensive effect.

*In which cases do you have to consult your doctor before taking ISOKET® retard 120 mg?*

The following section describes the cases in which ISOKET® retard 120 mg may be used only on certain conditions and only with observing particular caution and monitoring the patient. Please ask your doctor in such cases. This section is also relevant when the below-mentioned factors applied to you in the past.

Particular caution in using isosorbide dinitrate is necessary in:

- hypertrophic obstructive cardiomyopathy (myocardial disease with reduction of the ventricular cavities), constrictive pericarditis, and cardiac tamponade;
- low filling pressures, e.g. in acute myocardial infarction, reduced function of the left ventricle (left ventricular failure). Decreasing the systolic blood pressure below 90 mm Hg should be avoided;
- narrowing of the aortic and/or mitral valve (aortic and/or mitral stenosis);
- tendency towards circulatory dysregulation because of low blood pressure (orthostatic dysfunction);
- 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).

ISOKET® retard 120 mg is not intended to treat sudden pain in the heart (acute anginal attack).

*What do you have to observe during pregnancy and lactation?*

For reasons of particular caution, isosorbide dinitrate should be used during pregnancy and lactation only by a physician's special order, because there is not sufficient experience with its use in pregnant and nursing women. Animal experiments have not yielded any indication of fetal damage.

## **WARNINGS AND SPECIAL PRECAUTIONS FOR USE**

*Which precautions have to be observed?*

*What do you have to observe when driving a motor-vehicle or operating machinery or working in places without secure hold?*

Even when used in accordance with the instructions, this drug can alter the patient's reaction rate to an extent such as to impair his/her ability to drive a motor-vehicle or to operate machinery or to work in unsafe places. This is particularly true when the therapy is started, the dose is raised or the preparation is changed, or when the preparation interacts with alcohol.

## **INTERACTIONS WITH OTHER DRUGS**

*Which other drugs affect the effect of ISOKET® retard 120 mg or are affected by ISOKET® retard 120 mg as to their effects?*

The concomitant use of other vasodilators, anti-hypertensives, beta blockers, calcium antagonists, neuroleptics or tricyclic antidepressants, and alcohol can enhance the hypotensive effect of ISOKET® retard 120 mg.

This is particularly true for the concomitant use of phosphodiesterase type 5 inhibitors, e.g. Viagra® (see "Contraindications" section).

When used together with dihydroergotamine (DHE), ISOKET® retard 120 mg may lead to an increase in the DHE level and thus enhance the hypertensive 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® retard 120 mg differently. Please observe the instructions for use, because ISOKET® retard 120 mg will not take full effect otherwise.

*At which dosage and how often should you use ISOKET® retard 120 mg?*

Take one prolonged-release capsule of ISOKET® retard 120 mg (equivalent to isosorbide dinitrate 120 mg) o.d.

*How and when should you use ISOKET® retard 120 mg?*

Take the capsules without chewing with sufficient liquid (e.g. a glass of water).

The therapy should be started at a low dose, which should then be raised slowly until it meets your demand.

*How long should you use ISOKET® retard 120 mg?*

The duration of therapy is determined by your doctor.

This drug is particularly suited for long-term therapy and should not be discontinued abruptly except by your doctor's order.

## **OVERDOSAGE AND FAULTY USE**

*What has to be done, if too much ISOKET® retard 120 mg has been used (intentional or accidental overdose)?*

Please inform a doctor immediately, if overdose with major amounts of ISOKET® retard 120 mg is suspected.

Dependent on the extent of overdose, there may be a great decrease in blood pressure (hypotension) with reflex elevation of the heart rate, a feeling of weakness, vertigo and dizziness, and headache, skin reddening, nausea, vomiting and diarrhoea.

## **SIDE EFFECTS**

*What side-effects may appear during the use of ISOKET® retard 120 mg?*

Headache ("nitrate headache") commonly occurs when the treatment begins; experience has shown it to subside in most cases after few 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 posture (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 reddening (flushing), and allergic skin reactions are rare.

Rarely a marked decrease in blood pressure may lead to an exacerbation of the anginal symptoms. States of collapse, sometimes associated with cardiac arrhythmias with a reduction of heart rate (bradycardic arrhythmias) and sudden loss of consciousness (syncope), are seldom seen.

Exfoliative dermatitis (inflammation of the skin) may occur in rare cases.

The development of tolerance (decrease in effect) as well as cross-tolerance towards other nitro substances (decrease in effect due to a prior therapy with other nitrate drugs) have been described. Continuously high dosages should be avoided in order not to provoke a decrease in, or loss of, effect.

#### **NOTE:**

Due to a relative redistribution of blood flow into hypoventilated alveolar areas of the lungs, the use of ISOKET® retard 120 mg can result in temporary reductions of the content of oxygen in the arterial blood (hypoxaemia) and may induce underperfusion of the myocardium (myocardial hypoxia) 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?*

If you observe any of the above-mentioned side-effects, please inform your doctor so he can de-

cide on their severity and on any measures that may be necessary.

No additional dose of ISOKET® retard 120 mg must be taken, once the first signs of hypersensitivity appear.

#### **NOTES AND SHELF-LIFE INFORMATION**

The expiry date of this package has been printed on the blister-strip and the folding box.

Do not use the drug after the expiry date.

Please take always care to store ISOKET® retard 120 mg capsules so that they are out of the reach of children!

#### **DATE OF THIS INFORMATION**

September 2002

#### **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**

**SCHWARZ**  
P H A R M A