

# isoket<sup>®</sup> retard 40

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<sup>®</sup> retard 40

Active ingredient: isosorbide dinitrate

### COMPOSITION

*Pharmaceutically active ingredients:*

One sustained release tablet of isoket<sup>®</sup> retard 40 contains isosorbide dinitrate 40 mg.

*Other ingredients:*

Talcum, polyvinyl acetate, magnesium stearate, lactose 1 H<sub>2</sub>O, potato starch

### PRESENTATION AND CONTENTS

Packs of 30 (N1), 50, 60 (N2) and 100 (N3) sustained release tablets, hospital-size packs of 350 (5 x 70) and 500 sustained release tablets

*Substance group/mode of action*

Organic nitrates

### NAME AND ADDRESS OF THE PHARMACEUTICAL MANUFACTURER:

SCHWARZ PHARMA AG

Alfred-Nobel-Str. 10

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## INDICATIONS

- Long-term therapy of disturbances of coronary blood flow (coronary heart disease)
- Prophylaxis of anginal attacks (chest pain)
- Follow-up therapy of myocardial infarction in the presence of anginal complaints
- Therapy of severe myocardial insufficiency (chronic heart failure), in combination with cardiac glycosides and/or diuretics

## CONTRAINDICATIONS

*When must you not use isoket<sup>®</sup> retard 40?*

isoket<sup>®</sup> retard 40 must not be used in cases of:

- allergy to nitrate-type drugs;
- acute myocardial infarction with low filling pressures;
- acute circulatory failure (shock, circulatory collapse);
- very low blood pressure (marked hypotension: systolic blood pressure <90 mm Hg);
- cardiogenic shock, unless a sufficiently high left ventricular end-diastolic pressure is ensured by intra-aortic counterpulsation or positive inotropic drugs.

During a therapy with isoket<sup>®</sup> retard 40, no phosphodiesterase type 5 inhibitors such as Viagra<sup>®</sup> must be taken because this may result in a severe blood pressure lowering effect.

*In which cases do you have to consult your doctor before taking isoket<sup>®</sup> retard 40?*

The following section describes the cases in which isoket<sup>®</sup> retard 40 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:

- aortic and/or mitral stenosis (narrowing of the aortic and/or mitral valve);
- tendency towards orthostatic circulatory dysregulation (circulatory dysregulation in the presence of too low blood pressure);
- 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).

isoket<sup>®</sup> retard 40 is not intended for the treatment of an acute anginal attack.

*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?*

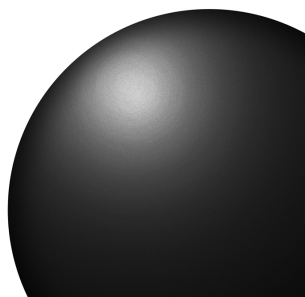
Even when used in accordance with the instructions, this drug can alter the reactivity such as to impair the ability required to drive a motor-vehicle, to operate machinery or to work in unsafe places. This is particularly true when the therapy is started, the dose is raised, the drug is changed or the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

## INTERACTIONS WITH OTHER DRUGS

*Which other drugs affect the effect of isoket<sup>®</sup> retard 40?*

The concomitant use of antihypertensives, calcium antagonists, neuroleptics, other vasodilators, beta blockers or tricyclic antidepressants, and alcohol can enhance the blood pressure lowering effect of isoket<sup>®</sup> retard 40.

This is true in particular for the concomitant use of phosphodiesterase type 5 inhi-



bitors such as Viagra® (see „Contraindications“).

*How are the effects of other drugs affected by isoket® retard 40?*

When used together with dihydroergotamine, isoket® retard 40 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® retard 40 differently. Please observe the instructions for use, because isoket® retard 40 will not take full effect otherwise.

*How should you take isoket® retard 40?*

At the beginning of therapy, take 1 sustained release tablet of isoket® retard 40 once daily or 1/2 tablet twice daily independently of meals without chewing and together with liquid. In cases of greater demands for nitrate, the dose can be raised to 1 tablet of isoket® retard 40 twice daily. If the dosage is one sustained release tablet of isoket® retard 40 twice daily, the second tablet should be taken no later than 8 hours after the first one for the full effect of the drug to be maintained.

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



The therapy should be started with a low dose which will be increased slowly to meet the demand. Your doctor will decide on how long the therapy is to be continued. This drug is particularly suitable for 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® retard 40?*

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 reddening (flushing), and allergic skin reactions are rare.

Infrequently a marked general decrease in blood pressure results in so great a reduction of coronary blood flow that an exacerbation of the anginal symptoms can be 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 nitrate-type drugs) was described. A loss of drug effect (decrease in hemodynamic effects) was already observed within 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® retard 40 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**

Juni 2005

### **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**  
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