

## **Package leaflet: Information for the patient**

### **Isosorbe 40 mg prolonged-release tablets Isosorbe 60 mg prolonged-release tablets**

*(isosorbide mononitrate)*

**Read all of this leaflet carefully before you start taking 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. See section 4.

#### **What is in this leaflet**

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

#### **1. What Isosorbe is and what it is used for**

Isosorbe contains a medicine called isosorbide mononitrate. This belongs to a group of medicines called 'nitrates'. They act on the cardiovascular system (heart and blood vessels). It is used to prevent chest pain (angina). Prolonged-release tablets are made so that they release the medicine slowly over a number of hours.

In angina, isosorbide mononitrate works by dilating the arteries that supply blood and oxygen to the heart muscle and reducing the risk of angina (chest pain), which occurs when the heart is loaded.

#### **2. What you need to know before you take Isosorbe**

##### **Do not take Isosorbe:**

- If you are allergic to isosorbide mononitrate, other nitrates (glyceryl trinitrate or isosorbide dinitrate) or any of the other ingredients of this medicine (listed in section 6).
- If you are taking sildenafil, vardenafil or tadalafil used for treatment of erectile dysfunction;
- If you have very low blood pressure (systolic pressure lower than 90 mm Hg);
- If you have an acute and sharp drop in blood pressure (circulatory collapse, cardiogenic shock).

##### **Warnings and precautions**

Talk to your doctor before taking Isosorbe if:

- you have narrowed heart valves;
- you get dizzy or faint when standing up (orthostatic hypotension);
- you have a brain disease associated with increased pressure in the cranial cavity;
- you have an acute attack of chest pain (acute angina), an acute heart attack or weakness of the heart muscle (left ventricular failure);
- you have disease and enlargement of the heart muscle, thickening of the lining of the heart (hypertrophic obstructive cardiomyopathy, constrictive pericarditis) or the lining of the heart is

filled with fluid (pericardial tamponade).

Isosorbe may cause a transient decrease in oxygen flow to the heart muscle and increase the intensity of chest pain. If your complaints get worse during treatment with Isosorb, tell your doctor immediately.

### **Other medicines and Isosorbe**

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

- medicines for high blood pressure (e.g. beta-blockers, calcium antagonists);
- medicines from the group of tricyclic antidepressants for the treatment of depression;
- medicines from the group of neuroleptics for the treatment of certain mental illnesses.

Taking these medicines with Isosorbe may increase the risk of low blood pressure.

Do not take sildenafil, vardenafil and tadalafil for the treatment of erectile dysfunction together with Isosorbe. This can lead to a severe drop in blood pressure.

Tell your doctor if you are taking medicines containing dihydroergotamine (used to treat migraine), together with Isosorbe as this can lead to an excessive increase your blood pressure.

### **Isosorb intake with food, drink and alcohol**

Do not drink alcohol at the same time as Isosorbe, as there is a risk of excessive blood pressure, dizziness, drowsiness or dizziness.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no clinical data on the use of Isosorbe during pregnancy. Isosorbe should be used in pregnant women only at the discretion of the physician if the potential benefit to the pregnant woman outweighs the risk to the fetus.

### **Driving and using machines**

Dizziness, drowsiness or fatigue may occur during treatment with Isosorbe, especially at the beginning of treatment, when increasing the dose, switching to other medicines or taking alcohol. This must be taken into account when driving or operating machinery.

### **Isosorbe contains lactose**

Isosorbe contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Isosorbe.

## **3. How to take Isosorbe**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The capsules should be swallowed whole without chewing with enough water (e.g. a glass of water).

Your doctor will decide what initial dose you should take and whether it needs to be increased depending on your condition and whether you are taking any other medicines. Do not change the dose unless your doctor tells you.

***Use in children:***

In children, the safety and effectiveness of the product have not been proven.

**If you take more Isosorbe than you should**

If you take more Isosorbe than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the tablets can be identified.

**If you forget to take Isosorbe**

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Isosorbe**

Do not stop suddenly taking your medicine. Your doctor will explain how to reduce the dose and then stop taking Isosorbe.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may happen with this medicine is headaches. Headache may affect between 1 and 10 patients in 10 treated and decreases gradually with time and duration of use.

**Other possible side effects:**

Common (may affect up to 1 in 10 people):

- Dizziness;
- Fatigue.

Uncommon (may affect up to 1 in 100 people):

- Drowsiness;
- Worsening of chest pain, slow and irregular heartbeat (bradyarrhythmia), drop in blood pressure when standing up, which causes dizziness, fainting or fainting (orthostatic hypotension), rapid heartbeat;
- Short-term fainting or fainting (syncope), excessive drop in blood pressure and deterioration of blood circulation);
- Nausea, vomiting;
- Skin rash (exfoliative dermatitis, allergic skin reactions);

**Reporting of side effects:**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system of Bulgarian Drug Agency.

**Contacts:**

Bulgarian Drug Agency  
8 Damyan Gruev Str.,  
1303 Sofia.  
Tel.: +359 2 890 3417  
Website: [www.bda.bg](http://www.bda.bg)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Isosorbe**

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. 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 Isosorbe contains**

- The active substance is: isosorbide mononitrate.
- The other ingredients are: hypromellose, carnauba wax, stearic acid, lactose monohydrate, magnesium stearate; for the shell: talc, hypromellose, titanium dioxide, magnesium stearate, colloidal anhydrous silica, macrogol 400, yellow iron oxide (E172).

### **What Isosorbe looks like and contents of the pack**

#### **Isosorbe 40 mg prolonged-release tablets**

Round biconvex cream tablets marked "IM40" on one side.

10 pieces in a blister of PVC/PVDC aluminum foil. 3 blisters in one package and a leaflet for the patient.

#### **Isosorbe 60 mg prolonged-release tablets**

Cream-colored elliptical tablets with a score line on both sides and a "60" mark on one side.

10 pieces in a blister of PVC/PVDC aluminum foil. 3 blisters in one package and a leaflet for the patient.

### **Marketing Authorisation Holder and Manufacturer**

Tchaikapharma High Quality Medicines Inc.

1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria

Tel.: + 359 2 962 54 54

FAX: + 359 2 9603 703

e-mail: info@tchaikapharma.com

*For any information about this medicine, please contact the local representative of the Marketing Authorization Holder..*

Tchaikapharma High Quality Medicines Inc.

1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria

Tel.: + 359 2 962 54 54

FAX: + 359 2 9603 703

e-mail: info@tchaikapharma.com

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