

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

### **Verapamil-Tchaikapharma 40 mg coated tablets Verapamil-Tchaikapharma 80 mg coated tablets**

*(Verapamil hydrochloride)*

**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. This includes any possible side effects not listed in this leaflet. See section 4.

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

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

#### **1. What Verapamil-Tchaikapharma is and what it is used for**

The name of your medicine is Verapamil-Tchaikapharma coated tablets. The active ingredient is verapamil hydrochloride.

Verapamil is a calcium antagonist. It exerts its pharmacological action by altering the entry of calcium ions through the cell membrane of the arterial smooth muscle, and dilates the large coronary arteries, thus improving blood flow.

Enlargement of vessels facilitates pumping of blood from the heart to the rest of the body with the possibility of delivering more oxygen to the heart muscle and a decrease in blood pressure.

Verapamil-Tchaikapharma is used for the treatment of:

- ischemic heart disease (conditions characterized by insufficient oxygen supply to the heart muscle);
- cardiac arrhythmias (such as paroxysmal supraventricular tachycardia and atrial fibrillation / rapid atrioventricular fibrillation with the exception of Wolff-Parkinson-White or Lown-Ganong-Levine syndromes);
- high blood pressure (hypertension).

#### **2. What you need to know before you take Verapamil-Tchaikapharma**

**Do not take Verapamil-Tchaikapharma, if:**

- you are allergic to the active substance (verapamil) or any of the other ingredients of this medicine (see section 6);
- you have cardiac conduction of the heart (second or third degree heart except for patients with a functioning pacemaker);
- you have “sick sinus syndrome” (except for patients with a functioning pacemaker);
- you have congestive heart failure (most often manifested by shortness of breath, fatigue, swelling of the legs);

- you have heart rhythm disturbances (atrial fibrillation/flutter and an additional conduction pathway such as Wolff-Parkinson-White syndrome or Lown-Ganong-Levine syndrome);
- you are being treated with ivabradine (for heart conditions);
- your blood pressure is extremely low as a result of severe heart problems (such as during shock).

If you are not sure about anything, ask your doctor.

### **Warnings and precautions**

Talk to your doctor before taking Verapamil-Tchaikapharma.

Verapamil-Tchaikapharma is used with caution in patients with:

- acute myocardial infarction (heart attack);
- first degree AV block;
- low blood pressure (hypotension);
- slow heart rate;
- heart failure;
- severe hepatic impairment;
- end-stage renal dysfunction;
- you have any neuromuscular diseases (myasthenia gravis, Lambert-Eaton syndrome, advanced Duchenne muscular dystrophy).

### **Other medicines and Verapamil-Tchaikapharma**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any of the following medicines.

Be sure to tell your doctor if you are taking any of the following medicines that may interact with Verapamil-Tchaikapharma:

- alpha blockers (prazosin, terazosin) and beta-blockers (propranolol, metoprolol);
- medicines used to treat high blood pressure, heart conditions or heart failure (flecainide, quinidine, digoxin, digitoxin);
- medicines used to treat increased uric acid (sulfapyrazone);
- medicines to treat gout attacks (colchicine);
- medicines used to treat certain type of infections (rifampicin, erythromycin, telithromycin, clarithromycin) and immunological drugs (ciclosporin, everolimus, sirolimus, tacrolimus);
- medicines used to lower cholesterol levels (simvastatin, lovastatin or atorvastatin);
- medicines to treat cancer - doxorubicin;
- medicines affecting the nervous system and psyche (phenobarbital, phenytoin, carbamazepine, imipramine, buspirone, midazolam, almotriptan, lithium);
- cimetidine, used to treat indigestion or stomach ulcers;
- glyburide, used to treat certain types of diabetes;
- theophylline, used to treat asthma;
- medicines known as “direct oral anticoagulants” such as dabigatran;
- ivabradine, used to treat heart conditions;
- ritonavir, used to treat HIV;
- acetylsalicylic acid;
- diuretics (water tablets);
- vasodilators;
- Hypericum perforatum (St John’s Wort).

Verapamil may decrease the glucose-lowering effect of metformin.

### **Verapamil-Tchaikapharma with food, drink and alcohol**

#### Alcohol

Verapamil-Tchaikapharma can increase the amount of alcohol in the body and the time it takes for alcohol to leave the body. Therefore, the effects of alcohol can be enhanced.

### Grapefruit juice

Do not drink grapefruit juice whilst taking Verapamil-Tchaikapharma. Grapefruit juice can affect the absorption of verapamil. This in turn may increase the risk of side effects when using Verapamil-Tchaikapharma.

### **Pregnancy and breast-feeding**

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

There are no adequate data from the use of verapamil in pregnant women. The drug can be used in pregnant women only in cases of absolute necessity determined by your doctor. Verapamil crosses the placenta and is measured in the blood from the umbilical cord.

Verapamil is excreted in breast milk. Due to the risk of adverse reactions for the newborn, verapamil should be used during breast-feeding only if it is essential for the mother's health.

### **Driving and using machines**

In sensitive patients, Verapamil-Tchaikapharma may affect reactions in terms of the ability to drive or use machines, as well as the ability to work in potentially hazardous conditions. This is especially true at the beginning of treatment, when increasing the dose, when switching from one drug to another, as well as when consuming alcohol.

### **Important information about some of the ingredients of Verapamil-Tchaikapharma**

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Verapamil-Tchaikapharma**

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

Your doctor will determine the dose of Verapamil-Tchaikapharma you should take, depending on the severity of the disease. The average daily dose is between 240 and 360 mg. The daily dose should not exceed 480 mg with long-term use, although higher doses may be used for a short period of time. There are no restrictions on the duration of application. With long-term use, Verapamil-Tchaikapharma should not be discontinued suddenly. Gradual dose reduction is recommended.

### Adults

*Ischemic heart disease, paroxysmal supraventricular tachycardia and atrial fibrillation / flutter:*  
Daily dose of 120 to 480 mg Verapamil-Tchaikapharma, taken in three or four separate doses.

### *Hypertension (high blood pressure)*

Daily dose of 120 до 480 mg Verapamil-Tchaikapharma, taken in three separate doses.

### **Children and adolescents**

- up to 6 years of age: daily dose of 80-120 mg Verapamil-Tchaikapharma, taken in two to three separate doses;
- 6-14 years of age: daily dose of 80 to 360 mg Verapamil-Tchaikapharma, taken in two to four separate doses.

### *Route of administration*

It is administered orally. The coated tablets should be swallowed whole with some liquid.

### **If you take more Verapamil-Tchaikapharma than you should**

If you or someone else accidentally takes more than the required dose of Verapamil-Tchaikapharma (a situation known as an overdose), contact your doctor immediately or go to the nearest hospital, taking the medicine pack with you.

#### **If you forget to take Verapamil-Tchaikapharma**

You must take Verapamil-Tchaikapharma as prescribed. However, if you miss a dose, take it as soon as you remember, unless it is almost time for your next dose. Then take the next dose straight away. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Verapamil-Tchaikapharma**

It is important that you take the tablets until your doctor tells you to stop. Do not stop taking the tablets, even if you feel well. If you stop your treatment, your condition may get worse.

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

## **4. Possible side effects**

Like all medicines, Verapamil-Tchaikapharma can cause side effects, although not everybody gets them.

### **Possible side effects when taking Verapamil-Tchaikapharma:**

#### Common (may affect up to 1 and 10 patients in every 100 treated):

- headache;
- dizziness;
- slow heartbeat;
- low blood pressure;
- flushing;
- constipation;
- nausea (feeling sick);
- swollen feet or ankles.

#### Uncommon (may affect up to 1 and 10 patients in every 1 000 treated):

- irregular heartbeat;
- fast heartbeat;
- stomach pain;
- tiredness.

#### Rare (may affect up to 1 and 10 patients in every 10 000 treated):

- numbness, tingling in the skin of hands and feet (paresthesia);
- tremor;
- drowsiness;
- a ringing sound in the ears (tinnitus);
- vomiting;
- sweating a lot more than usual.

#### Not known (frequency cannot be estimated from the available data):

- hypersensitivity;
- severe allergic reaction that cause swelling of the face and through (angioedema);
- seizures;
- paralysis;
- a condition characterized by trembling, stiffness and weakness of the legs (extrapyramidal disorders);
- vertigo;
- disorders of heart rate and conduction - atrio-ventricular block (1st, 2nd and 3rd degree);

- heart disease, which leads to easy fatigue, shortness of breath, swelling of the ankles, etc. (heart failure);
- slow heart rate (sinus bradycardia), cardiac arrest (asystole, sinus arrest);
- bowel obstruction;
- stomach discomfort;
- swollen gums;
- joint pain;
- muscle weakness;
- muscle pain;
- rash;
- itching;
- hives;
- hair loss (alopecia);
- severe disease accompanied by blistering of the skin, mouth, eyes and genitals (Stephen-Johnson syndrome);
- skin disease such as erythema multiforme;
- erectile dysfunction;
- breast enlargement in men (gynecomastia);
- separating of whitish to milky white secretions from the breast without being associated with pregnancy, childbirth or breastfeeding (galactorrhea);
- high levels of potassium in the blood, which may cause changes in heart rhythm (hyperkalaemia);
- difficulty breathing or wheezing (bronchospasm);
- difficulty in breathing;
- kidney problems;
- increase in liver enzymes;
- greater than normal amounts of prolactin in the blood.

### **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:

Bulgarian Drug Agency  
 8 Damyan Gruev Str.,  
 1303 Sofia  
 Tel.: +359 28903417  
 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 Verapamil-Tchaikapharma**

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

Store in a dark, dry place at temperatures below 25 °C.

Do not use this medicine after the expiry date which is stated on the carton. 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 Verapamil-Tchaikapharma 40 mg contains**

- The active substance is verapamil hydrochloride
- The other ingredients are: lactose monohydrate, potato starch, croscarmellose sodium, talc, silica colloidal anhydrous, magnesium stearate, corn starch, povidon, carmellose sodium, sucrose, polysorbate, calcium carbonate, titanium dioxide, colorant quinolone yellow E104, capol 600.

**What Verapamil-Tchaikapharma 80 mg contains**

- The active substance is verapamil hydrochloride
- The other ingredients are: lactose monohydrate, corn starch, sodium starch glycolate, hydroxypropylcellulose, microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate, talc, sucrose, titanium dioxide, povidon, macrogol 6000, acacia, colorant quinolone yellow E104, opaglos white 6000.

**What Verapamil-Tchaikapharma 40 mg looks like and contents of the pack**

Each blister contains 15 coated Verapamil-Tchaikapharma tablets. One cardboard box contains 2 blisters (30 tablets in total) and a patient leaflet.

**What Verapamil-Tchaikapharma 80 mg looks like and contents of the pack**

Blister Aluminium/PVC foil

50 coated tablets (5 blisters x 10 coated tablets) in a cardboard box.

**Marketing Authorisation Holder and Manufacturer**

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Fax: 02/ 960 37 03  
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For any information about this medicine, please contact the Marketing Authorization Holder.

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