

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### TRIMETACOR

35mg Prolonged-release tablet

#### TRIMETAZIDINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

1. What TRIMETACOR is and what it is used for
2. Before you take TRIMETACOR
3. How to take TRIMETACOR
4. Possible side effects
5. How to store TRIMETACOR
6. Further information

#### 1. WHAT TRIMETACOR IS AND WHAT IS IT USED FOR

Trimetazidine protects cell metabolism in a state of hypoxia or ischemia, or decreased oxygen supply, and maintains cell function. This medicine is used in adults, in combination with other drugs for the treatment of angina pectoris (chest pain caused by heart disease).

#### 2. BEFORE YOU TAKE TRIMETACOR

##### **Do not take TRIMETACOR**

- If you are allergic to trimetazidine or any of the other ingredients of this medicine (listed in section 6);
- If you have Parkinson's disease, brain disease affecting movement (shaking, frozen posture, slow movements and shuffling gait unbalanced);
- If you have severe kidney problems.

##### **Take special care with TRIMETACOR**

Talk to your doctor or pharmacist before taking TRIMETACOR.

This medicine is not recommended during pregnancy or breastfeeding.

This product should be administered with caution in patients with a predisposition to glaucoma;

This drug is not a treatment for angina, and is not recommended for initial treatment of unstable angina or acute myocardial infarction. In case of angina, the disease should be reassessed and discuss a change of treatment (medication, the possibility of revascularization if necessary).

This medicine may cause or worsen symptoms such as trembling, frozen posture, slow movements and shuffling gait unbalanced, especially in elderly patients who should be tested and reported to your doctor, who may review treatment.

### **Children**

Trimetakor not recommended for children under 18 years.

### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Taking the medicine TRIMETACOR with food and drink**

The tablets should be swallowed with a glass of water at mealtimes.

### **Pregnancy and breastfeeding**

It is preferable not to take this medicine during pregnancy.

If you become pregnant while taking this medicine, consult your doctor as only he can assess the need for continued treatment.

In the absence of data transmission of the drug in human milk, breastfeeding is not recommended during treatment.

If you are pregnant or breast-feeding, you think you may be pregnant or planning to become pregnant, ask your doctor or pharmacist before taking this medicine.

### **Driving and using machines**

TRIMETACOR Tablets can affect your ability to drive or operate machinery. This medicine may cause dizziness and drowsiness and can affect your ability to drive or operate machinery.

### **Important information about some of the ingredients of TRIMETACOR**

Not implacable.

## **3. HOW TO TAKE TRIMETACOR**

Always take TRIMETACOR exactly as indicated in this package leaflet. If you are unsure, please ask your doctor or pharmacist for advice.

The recommended dose is one tablet Trimetakor 35 mg twice a day, during the morning and evening meals.

If you have kidney problems or are older than 75 years your doctor may change your recommended dose.

The benefit of treatment should be reassessed after three months and a possible lack of response, treatment should be discontinued.

### **If you take more TRIMETACOR than you should**

If you take a higher dose of Trimetakor than your doctor prescribes, immediately tell your doctor or pharmacist.

### **If you forget to take TRIMETACOR**

If you miss a dose, take the tablets as soon as you remember and carry on as before. If it is almost time for your next dose, skip the missed dose and continue as usual (do not take a double dose to make up for the forgotten dose).

***If you stop taking TRIMETACOR***

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

***4. POSSIBLE SIDE EFFECTS***

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

**Common:**

Dizziness, headache, abdominal pain, diarrhea, indigestion, nausea, vomiting, rash, itching, hives, and feeling faint.

**Rare:**

Fast or irregular heartbeat (also called palpitations), rapid heartbeat, drop in blood pressure upon standing, causing dizziness, fainting or dizziness, malaise (feeling of general weakness), dizziness, falls, sudden reddening of the face ("flush").

**Not known:**

Extrapyramidal symptoms (abnormal movements, which include tremors (incl. The hands and fingers), undulating body movements, dragging gait, stiffness in the arms and legs), which are usually reversible upon discontinuation of treatment; Sleep disturbance (difficulty falling asleep, sleepiness), constipation, serious generalized red skin rash with blisters, swelling of the face, lips, mouth, tongue or throat that may cause difficulty in swallowing or breathing; Sharply reducing the number of white blood cells, which predisposes to infections, reduced platelet blood, increasing the risk of bleeding or bruising; Liver disease (nausea, vomiting, loss of appetite, feelings of malaise, fever, itching, yellowing of the skin and eyes, light colored stools, dark urine).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

***5. HOW TO STORE TRIMETACOR***

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Expiration date:

3 years

Store below 30 °C. Store in the original container to protect from moisture and light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

***6. FURTHER INFORMATION***

***What TRIMETACOR contains***

The active substance is trimetazidine.

Each prolonged-release tablet contains trimetazidinov dihydrochloride, equivalent to 35 mg of trimetazidine.

Other ingredients are:

Core: sodium chloride, povidone (K30), magnesium stearate

Coating: cellulose acetate (CA-398-10) and Hypromellose 6 cps

***What TRIMETACOR looks like and contents of the pack***

White to off-white, round biconvex tablets, plain on both sides with aperture on the side.

PVC / PVDC-aluminum blister.

3 blisters with 20 tablets.

Box of 60 tablets.

***Regime of dispensing***

The medicine is issued on prescription.

***Manufacturer***

Alvogen doo Barice, Pašnjačka bb, Barice, municipality of Plandište, Serbia

***Manufacturer of the medicinal product***

Alvogen doo Barice, Pašnjačka bb, Barice, municipality of Plandište, Serbia, or

Pharma Pack Hungary Ltd., H-2040 Budaors, Vasút u.13 Hungary, or

S.C. LABORMED-PHARMA SA, 44B Theodor Pallady Blvd., 3rd district, Bucharest, Romania, or

Extractum Pharma Zrt., 6413 Kunfehértó, IV, corset 6, Hungary