**Package leaflet: Information for the patient**

**Betaloc ZOK 25, 23.75 mg, prolonged release tablets**
**Betaloc ZOK 50, 47.5 mg, prolonged release tablets**
**Betaloc ZOK 100, 95 mg, prolonged release tablets**
*Metoprololi succinas*

**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 Betaloc ZOK is and what it is used for

Betaloc ZOK contains active substance called metoprolol, which belongs to a group of medicines known as beta-blockers.
Metoprolol reduces the effect of stress hormones on the heart during physical exercise or mental strain. This slows down the heart rate (reduces pulse).

Betaloc ZOK is used in the **treatment of:**
- high blood pressure (hypertension), to reduce blood pressure and the risk of complications (such as heart attack or stroke) and cardiovascular death (including sudden death),
- tightening chest pain caused by insufficient oxygen supply to the heart (angina pectoris),
- irregular heart beat (arrhythmia), especially supraventricular tachycardia, extrasystoles of ventricular origin and atrial fibrillation to slow down ventricular rate,
- palpitations (feeling your heart beat) caused by non-organic (functional) heart disorders,
- chronic heart failure (with such symptoms as shortness of breath and swollen ankles), together with other medicines taken for heart failure to increase survival, reduce hospitalisation, improve left ventricular function and quality of life.

Betaloc ZOK is used in the **prevention of:**
- another heart attack or sudden death following acute phase of heart attack,
- migraine attacks.

Betaloc ZOK is used in the treatment of high blood pressure in children and adolescents from 6 to 18 years of age.

## 2. What you need to know before you take Betaloc ZOK

**Do not take Betaloc ZOK**
- if you are allergic to metoprolol tartrate or any of the other ingredients of this medicine (listed in section 6).

- if you are allergic to other beta-blockers e.g. atenolol, propranolol.
- if you have the following conditions:
  - cardiogenic shock,
  - sick sinus syndrome (unless you have a pacemaker),
  - 2nd or 3rd degree atrioventricular block,
  - untreated heart failure (shortness of breath, swollen ankles),
  - bradycardia (slow heart rate of less than 45 beats per minute),
  - very low blood pressure which may cause fainting,
  - severe blood circulation disturbances in peripheral arteries,
  - metabolic acidosis,
  - untreated phaeochromocytoma of adrenal glands,
  - suspected acute myocardial infarction, if heart rate is lower than 45 beats per minute, PQ interval exceeds 0.24 s or if systolic blood pressure is lower than 100 mmHg.
- if you receive short- or long-term treatment with inotropic medicines which stimulate beta-adrenergic receptors.

**Warnings and precautions**
Talk to your doctor before taking Betaloc ZOK. Tell your doctor if you have any of the following:
- bronchial asthma, wheezing or other similar breathing problems or allergic reactions, e.g. to insect stings, certain foods or other substances. If you have ever had an asthma attack or wheezing, you should not take this medicine before talking to your doctor first,
- chest pain caused by Prinzmetal's angina,
- circulation disorders or heart failure,
- liver problems,
- 1st degree heart block (heart conduction disorder),
- intermittent claudication (feeling that one or both of your legs are tired and weak when walking),
- diabetes mellitus (your doctor may advise a change in the dosing of your antidiabetic medications),
- hyperthyroidism – Betaloc ZOK may mask symptoms of overactive thyroid gland,
- phaeochromocytoma of adrenal glands,
- psoriasis.

Talk to your doctor even of these warnings apply to situations occurring in the past.

Before you are given any anaesthesia, tell your dentist or anaesthetist that you are being treated with Betaloc ZOK.

Do not stop treatment with Betaloc ZOK abruptly. If you have to stop taking Betaloc ZOK, it should be done gradually, if possible over at least two weeks. You should take decreasing doses until the last reduction of a 25 mg tablet to half a tablet, taken for at least four days before complete discontinuation of the drug.

**Other medicines and Betaloc ZOK**
Tell your doctor if you are taking, have recently taken or might take any other medicines. This also includes eye drops, injection medicines, over-the-counter drugs including herbal products and food supplements. Some medicines may affect the action of other drugs. Tell your doctor of you are taking any of the following:
- Medicines used in the treatment of cardiovascular diseases (such as digitalis/digoxin, calcium antagonists, antiarrhythmics, sympathetic ganglion blockers, hydralazine).
- Other medicines such as monoamine oxidase (MAO) inhibitors, inhalation anaesthetics, antibacterial medicines (rifampicin), medicines used to treat ulcers (cimetidine), anti-inflammatory drugs (e.g. indomethacin, celecoxib), certain antidepressants and antipsychotics, antihistamines, other beta-blockers (e.g. eye drops) and other substances (e.g. alcohol, certain hormones).

- If you take clonidine together with Betaloc ZOK and stopping clonidine treatment is necessary, Betaloc ZOK should be discontinued a few days before stopping clonidine treatment. For more information on Betaloc ZOK discontinuation, see section "Warnings and precautions".
- If you take oral antidiabetic medicines, your doctor may need to change their dosing.

**Betaloc ZOK with food, drink and alcohol**
Drinking alcohol during treatment with metoprolol may increase the effects of this medicine.

**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.

*Pregnancy*
Betaloc ZOK should not be used during pregnancy unless benefits outweigh the risks for the foetus. Overall, beta-blockers, including metoprolol may cause foetal harm and preterm delivery.
If you become pregnant during treatment with Betaloc ZOK, tell your doctor as soon as possible.

*Breast-feeding*
You should not use Betaloc ZOK while breast-feeding your baby unless benefits outweigh the risks for the breast-fed infant.

**Driving and using machines**
Before driving or using machines you should check your individual reaction to Betaloc ZOK, because some patients may experience dizziness or tiredness affecting their psychomotor performance.

## 3. How to take Betaloc ZOK

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

Betaloc ZOK tablets (or halves of tablets) must not be chewed or crushed. Tablets should be swallowed with liquid.

Generally, Betaloc ZOK should be taken once daily, with or without food. Your doctor will tell you how and when you should take your Betaloc ZOK tablets.

***Hypertension***
Adults
The recommended dose of Betaloc ZOK for patients with mild to moderate hypertension is 50 mg once daily. For patients who do not respond to the 50 mg dose, your doctor may increase the dose to 100-200 mg once daily and (or) additionally use another antihypertensive medicine.

Children and adolescents
In children and adolescents above 6 years of age, the dose depends on body weight. The right dose will be determined by your doctor.
Usually, the recommended initial dose is 1 mg/kg, not more than 50 mg, given once daily in tablets which are as close as possible to the estimated dose.
The doctor may increase the dose to 2 mg/kg depending on the blood pressure response.

Betaloc ZOK should not be used in children under 6 years of age.

***Angina pectoris***
The recommended dose is 100-200 mg once daily. If necessary, Betaloc ZOK may be used together with other antianginal medications.

***Symptomatic chronic heart failure***
The dose will be determined by your doctor. The recommended initial dose is one 25 mg tablet given once daily for the first 2 weeks of treatment. In patients with more severe heart failure, a half of 25 mg tablet will be used once daily for the first week of treatment. Then, your doctor will double the dose every two weeks until 200 mg once daily dose or your maximum tolerated dose is reached.

***Cardiac arrhythmias***
The recommended dose of Betaloc ZOK is 100-200 mg once daily.

***Functional heart disorders with palpitations***
The recommended dose is 100 mg once daily. If necessary, your doctor may increase the dose to 200 mg once daily.

***Prevention of subsequent heart attack or sudden cardiac death after acute phase of myocardial infarction***
The recommended dose is 200 mg once daily.

***Prevention of migraine***
The recommended dos ranges from 100 mg to 200 mg once daily.

If you feel that the effect of Betaloc ZOK is too strong or too weak, contact your doctor or pharmacist.

**If you take more Betaloc ZOK than you should**
If you take more Betaloc ZOK than you should, contact your doctor immediately or go to the emergency department of your nearest hospital.

In case of severe overdose, the following symptoms may occur: slow or irregular heart rate, shortness of breath, swollen ankles, feeling your heart beat, dizziness, fainting, chest pain or tightness, cold skin, weak pulse, confusion, anxiety state, cardiac arrest, partial or complete unconsciousness / comma, feeling sick, being sick and cyanosis.

**If you forget to take Betaloc ZOK**
Do not take a double dose to make up for the forgotten tablet.
When you miss your Betaloc ZOK dose take your dose as soon as possible if less than 12 hours have passed since your scheduled dose. If you realize that you missed your dose 12 or more hours after your scheduled dose, just skip the missed dose and take your next dose at usual time.

## 4. Possible side effects

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

The following are the side effects which may occur during treatment with this medicine.

**Very common (may affect at least 1 in every 10 patients)**
- Fatigue.

**Common (may affect less than 1 in every 10 patients)**
- dizziness,
- headache,
- slower heart rate; you should tell your doctor who may need to reduce your dose or gradually discontinue treatment,
- palpitations,
- changes in blood pressure caused by changing body position (very rarely with fainting),
- breathlessness during physical exercise,
- feeling sick,
- stomach ache,
- diarrhoea,

- constipation,
- cold hands and feet.

**Uncommon (may affect less than 1 in every 100 patients)**
- depression,
- insomnia,
- nightmares,
- concentration disorders,
- somnolence,
- burning, tingling or numbness (paraesthesia),
- worsening of pre-existing heart failure,
- heart conduction disorders manifested in ECG (1st degree heart block),
- abrupt blood pressure decrease during heart attack (cardiogenic shock),
- bronchospasm,
- vomiting,
- skin rash,
- excessive sweating,
- muscle cramps,
- retrosternal pain,
- swelling,
- weight gain.

**Rare (may affect less than 1 in every 1,000 patients)**
- nervousness,
- anxiety states,
- vision disorders,
- dry and (or) irritated eyes,
- conjunctivitis,
- heart conduction disorders, heart rhythm disturbances, worsening of pre-existent atrioventricular block,
- fingers turning white, blue and finally red, with coexistent numbness and pain (Raynaud syndrome),
- rhinitis,
- dry mouth,
- hair loss,
- erection disorders (impotence),
- impaired liver function (seen in blood tests),
- positive anti-nuclear antibodies (antibodies used in the diagnosis of connective tissue diseases).

**Very rare (may affect less than 1 in every 10,000 patients)**
- gangrene (tissue necrosis) in patients with severely impaired peripheral circulation,
- reduced platelet count which may result in easy bruising,
- confusion,
- hallucinations,
- memory loss or impairment,
- taste disorders,
- ringing in the ears,
- worsening of intermittent claudication (pain of legs when walking),
- hepatitis,
- sensitivity to light,
- worsening of psoriasis,
- joint pain.

**Conditions which may get worse**
The following conditions may get worse during treatment with this medicine:

- shortness of breath, fatigue or swollen ankles (in case of heart attack). These are uncommon side effects which may occur in less than 1 in every 100 patients.
- psoriasis (skin disease), blood circulation disorders. These are rare side effects which are found in less than 1 in every 10,000 patients.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych
Al. Jerozolimskie 181C
02-222 Warszawa
tel.: +48 22 49 21 301
fax.: +48 22 49 21 309
e-mail: ndl@urpl.gov.pl
Side effects may also be reported to Marketing Authorisation Holder.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Betaloc ZOK

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

Do not store above 30°C.
Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton after: Expiry date (EXP:). The expiry date refers to the last day of that month.
Do not use this medicine if the package is damaged.

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 Betaloc ZOK contains**
- The active substance is metoprolol succinate.
- One tablet contains 23.75 mg, 47.5 mg and 95 mg of metoprolol succinate which corresponds to 25 mg, 50 mg and 100 mg of metoprolol tartrate.
- The other ingredients are: ethyl cellulose, hydroxypropyl cellulose, microcrystalline cellulose, colloidal silicon dioxide, sodium stearyl fumarate, hypromellose, paraffin, macrogol (6000), titanium dioxide.

**What Betaloc ZOK looks like and contents of the pack**
Betaloc ZOK 25
White to off-white oval tablets sized 5.5 mm x 10.5 mm, with a score line on both sides, marked „A/β" on one side. Tablet can be divided into equal doses.

Betaloc ZOK 50
White to off-white round tablets, 9 mm diameter, with a score line on one side, marked „A/mO" on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Betaloc ZOK 100

White to off-white round tablets, 10 mm diameter, with a score line on one side, marked „A/mS" on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/PVDC/Al calendar blisters in a cardboard box.
28 tablets – 2 blisters of 14 tablets each.

## Marketing Authorisation Holder and Manufacturer

### Marketing Authorisation Holder
Recordati Industria Chimica e Farmaceutica S.p.A.
Via Matteo Civitali 1
20148 Mediolan
Włochy

**Manufacturer**
AstraZeneca AB
S-151 85 Södertälje
Sweden

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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