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Summary Public Assessment Report

Generics

Metoprolol Zentiva 25 mg
Metoprolol Zentiva 50 mg
Metoprolol Zentiva 100 mg
Metoprolol Zentiva 200 mg

metoprolol

SK/H/0298/001-004/DC
Applicant: Zentiva, k.s., Czech Republic

Date: 07.02.2025

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Metoprolol Zentiva 25 mg prolonged-release tablets
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metoprolol; 25 mg, 50 mg, 100 mg and 200 mg; prolonged-release tablets

This is a summary of the public assessment report (PAR) for Metoprolol Zentiva. It explains how Metoprolol Zentiva was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Metoprolol Zentiva.

For practical information about using Metoprolol Zentiva, patients should read the package leaflet or contact their doctor or pharmacist.

What is Metoprolol Zentiva and what is it used for?

Metoprolol Zentiva is a 'generic medicine'. This means that Metoprolol Zentiva is similar to a 'reference medicine' already authorised in the Slovak Republic (SK) called Betaloc ZOK 25 mg, 50 mg, 100 mg prolonged-release tablets and in the Czech Republic (CZ) called Betaloc ZOK 200 mg prolonged-release tablets.

Metoprolol Zentiva is used in adults:

- to treat high blood pressure (hypertension), to reduce the risk of complications due to high blood pressure such as stroke, heart attack or early death,
- as long-term treatment after heart attack and prevention of re-current heart attack,
- to treat heart or chest pain brought on by stress or exercise in patients with coronary heart disease (angina pectoris),
- to treat heart failure (symptomatic mild to severe chronic heart failure) - in addition to other heart failure treatment, to help increase survival, reduce hospitalisation, improve left ventricular function, improve the stage of heart failure (according to NYHA classification) and improve quality of life,
- to treat heart rate disease (arrhythmia), especially rapid heartbeat in patients with heart disease (heart rate disturbances including supraventricular tachycardia),
- to treat symptoms of rapid or irregular heartbeat in patients without heart disease (palpitations),
- to prevent migraine.

Metoprolol Zentiva is used to treat high blood pressure in children and adolescents aged 6 18 years.

How does Metoprolol Zentiva work?

Metoprolol Zentiva contains metoprolol succinate and is one of a group of medicines called selective beta-blockers. Beta-blockers slow the heartbeat, lessen the force with which the heart

muscle contracts and reduce blood vessel contraction in the heart, brain, and throughout the body. Prolonged-release tablet of metoprolol from the tablet provides a uniform effect through the day in once daily regimen.

How is Metoprolol Zentiva used?

The pharmaceutical form of Metoprolol Zentiva is prolonged-release tablet and the route of administration is oral use.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration and the duration of treatment.

The recommended doses for **adults** are:

High blood pressure (hypertension)
Recommended dose for the patients with mild to moderate hypertension is 50 mg once daily. This can be increased if necessary to 100 to 200 mg once a day.

Maintenance treatment after myocardial infarction
200 mg once daily

Angina pectoris (chest pain)
100 − 200 mg once daily

Patients with stable heart failure
The dose will be adjusted individually. Recommended starting dose is 0,5 − 1 tablet of 25 mg once daily for first one to two weeks. Thereafter, the dose is recommended to be doubled every other week as needed to a maximum 200 mg daily or maximal tolerated dose.

Disturbances of cardiac rhythm (arrhythmia)
100-200 mg once daily

Functional heart disorders with palpitations
100 mg once daily
The doctor may increase the dose to 200 mg as needed.

Prevention of migraine
100 − 200 mg once daily

Use in children and adolescents
High blood pressure (hypertension)
Metoprolol Zentiva is not recommended for children under 6 years.
The doctor will calculate the dose for the child. The dosage depends on the weight of the child.

The recommended starting dose is 0,5 mg/kg once daily, not exceeding 50 mg. Doctor may increase the dose to 2 mg/kg once daily based on the blood pressure.

Metoprolol Zentiva prolonged-release tablet should be swalloved with liquid.

The medicine can only be obtained with a prescription.

What benefits of Metoprolol Zentiva have been shown in studies?

Because Metoprolol Zentiva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Betaloc ZOK. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Metoprolol Zentiva?

Because Metoprolol Zentiva is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of restrictions, see the package leaflet.

Why is Metoprolol Zentiva approved?

It was concluded that, in accordance with EU requirements, Metoprolol Zentiva has been shown to be comparable to reference medicine. Therefore, the SIDC decided that, as for reference medicine called Betaloc ZOK, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Metoprolol Zentiva?

A risk management plan has been developed to ensure that Metoprolol Zentiva is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Metoprolol Zentiva, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Metoprolol Zentiva

The marketing authorisation for Metoprolol Zentiva was granted on 23.10.2024.

The full PAR for Metoprolol Zentiva can be found on the website sukl.sk. For more information about treatment with Metoprolol Zentiva, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 02/2025.