Proposed packaging material		
Code	Betaloc ZOK-PI-03.01	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: RO-Change Event-0042096	
Code of previous version	N/A	
Changes	Postal Code Changes and Revision of PI to align with Product Information	
Reference	☐ CDS version:N/A ☐CPIL version:N/A	☐SmPC:N/A ☐country/version/date:N/A GRL approval:N/A
Name & Date	AS (26-Mar-2025)	

SUMMARY OF PRODUCT CHARACTERISTICS

BETALOC® ZOK 25 & 50 mg
Prolonged Release Tablet
Metoprolol Succinate

WARNINGS: ISCHEMIC HEART DISEASE

Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have occurred. When discontinuing chronically administered BETALOC ZOK, particularly in patients with ischemic heart disease, the dosage should be gradually reduced over a period of 1 - 2 weeks and the patient should be carefully monitored. If angina markedly worsens or acute coronary insufficiency develops, BETALOC ZOK administration should be reinstated promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken. Warn patients against interruption or discontinuation of therapy without the physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue BETALOC ZOK therapy abruptly even in patients treated only for hypertension."

NAME OF THE MEDICINAL PRODUCT

Betaloc® ZOK 25 mg prolonged release tablet
Betaloc® ZOK 50 mg prolonged release tablet

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 prolonged release tablet contains: 23.75 mg, 47.5 mg metoprolol succinate corresponding to 25 mg, 50mg metoprolol tartarte respectively.
For a complete list of excipients, see section "List of excipients".

PHARMACEUTICAL FORM

Prolonged release tablet

Prolonged release tablets 25 mg: White, oval with a size of 5.5 mm × 10.5 mm, bisected, marked A/ß. Prolonged release tablets 50 mg: White, round with a diameter of 9 mm, bisected, marked A/mO. The scoremark is not intended to divide the tablet into two equal doses. It is only intended to facilitate swallowing.

CLINICAL PARTICULARS

Therapeutic indications

- Hypertension,
- Angina pectoris
- Heart Failure, to reduce the risk of cardiovascular mortality and heart failure hospitalizations in patients with heart failure
- Maintenance treatment after myocardial infarction.

Posology and method of administration

Betaloc ZOK prolonged release tablets are given once daily, preferably in the morning. The prolonged release tablets can be divided. They must not be chewed or crushed. The tablets should be swallowed together with at least half a glass of liquid. Concomitant intake of food does not influence the bioavailability.
Dosage should be adjusted individually to avoid bradycardia. The following is valid as guidelines:

Hypertension

50-100 mg once daily. In patients not responding to 100 mg, the dose could be combined with other antihypertensive agents, preferably diuretics and calcium antagonists of the dihydropyridine type, or increased.

Angina pectoris

100-200 mg once daily. If needed, the dose can be combined with nitrates or increased.

Chronic heart failure

The dose of Betaloc ZOK should be individually adjusted in patients with chronic heart failure stabilized on other heart failure treatment. A recommended initial dose during the first two

weeks is a 25 mg tablet once daily. It is recommended that patients with NYHA functional classes III-IV begin with half a 25 mg tablet once daily the first week. It is recommended that the dose then be doubled every second week up to a maximum target dose of 200 mg Betaloc ZOK once daily (or to the highest tolerated dose). During long-term treatment the aim should be to reach 200 mg Betaloc ZOK once daily (or the highest tolerated dose).

At each dose level the patient should be carefully evaluated with regard to tolerability. In case of hypotension, decrease in concomitant medication may be necessary. Initial hypotension does not necessarily mean that the dose cannot be tolerated in chronic treatment, but the patient should be kept at the lower dose until stabilized.

Maintenance treatment after myocardial infarction

Long-term treatment with metoprolol in doses of 200 mg given once daily has been shown to reduce the risk of death (including sudden death), and to reduce the risk of reinfarction (also in patients with diabetesmellitus).

Impaired renal function

The elimination rate is insignificantly affected by renal function, and dose adjustment is therefore not needed in impaired renal function.

Impaired hepatic function

Usually Betaloc ZOK is given in the same dose to patients suffering from liver cirrhosis as to patients withnormal liver function. Only when there are signs of very severe impairment of liver function (e.g. shunt- operated patients), a dose reduction should be considered.

Elderly

Dose adjustment is not needed.

Contraindications

- Cardiogenic shock.
- Sick-sinus syndrome (provided there is no permanent pacemaker).
- AV-block of second and third degree.
- Patients with unstable, not compensated heart failure (pulmonary oedema, hypoperfusion or hypotension), and patients with continuous or intermittent inotropic therapy acting through beta- receptor agonism.
- Symptomatic bradycardia or hypotension. Metoprolol should not be given to patients with suspected acute myocardial infarction as long as the heart rate is < 45 beats/min, the P-

Q interval is > 0.24 sec or the systolic blood pressure is < 100 mm Hg.

- In the indication heart failure, patients with repeated supine blood pressure below 100 mmHg should be re-evaluated before treatment is initiated.
- Serious peripheral vascular disease with gangrene threat.
- Hypersensitivity to the active substance, to other beta-blockers or to any of the excipients specified insection 6.1.

Special warnings and special precautions for use

Intravenous administration of calcium antagonists of the verapamil-type should not be given to patients treated with ß-blockers.

Generally when treating patients with asthma, concomitant therapy with a ß2-agonist (tablet and/or inhalation) should be administered. The dosage of ß2-agonists may require adjustment (increase) when treatment with metoprolol CR/ZOK is started. The risk of metoprolol CR/ZOK interfering with ß2- receptors is however less than with conventional tablet formulations of ß1-selective blockers.

During treatment with metoprolol CR/ZOK, the risk of interfering with carbohydrate metabolism or masking hypoglycaemia is likely to be less than during treatment with conventional tablet formulations of ß1-selective blockers and much less than with non-selective ß-blockers.

Very rarely, a pre-existing A-V conduction disorder of moderate degree may become aggravated (possiblyleading to A-V block).

If the patients develop increasing bradycardia, metoprolol CR/ZOK should be given in lower doses or gradually withdrawn.

Metoprolol CR/ZOK may aggravate the symptoms of peripheral arterial circulatory disorders.

Where metoprolol CR/ZOK is prescribed for a patient known to be suffering from a phaeochromocytoma,an alpha-blocker should be given concomitantly.

Abrupt withdrawal of ß-blockade is hazardous especially in high-risk patients and should therefore not be done.

If there is a need to discontinue treatment with metoprolol CR/ZOK, this should preferably be done gradually over at least two weeks when the dose is reduced by half in each step down to the final step whena whole 25 mg tablet is reduced to a half tablet.

The final dose should be taken for at least four days before discontinuation. If symptoms occur, a slower withdrawal rate is recommended. Sudden withdrawal of ß-blockade may aggravate chronic heart failure and also increase the risk of myocardial infarction and sudden death.

Prior to surgery the anesthetist should be informed that the patient is receiving metoprolol CR/ZOK. It is not recommended to stop ß-blocker treatment in patients undergoing surgery.

Acute initiation of high-dosemetoprolol to patients undergoing non-cardiac surgery should be avoided, since it has been associated withbradycardia, hypotension and stroke including fatal outcome in patients with cardiovascular risk factors.
In patients taking ß-blockers anaphylactic shock assumes a more severe form and may be resistant to usualdoses of adrenaline. Whenever possible, ß-blockers should be avoided in patients who are at increased riskof anaphylaxis

Interactions with other medicinal products and other forms of interaction
Metoprolol is a CYP2D6-substrate. Drugs that inhibit CYP2D6 can have an effect on the plasma concentration of metoprolol. Examples of drugs that inhibit CYP2D6 are quinidine, terbinafine, paroxetine, fluoxetine, sertraline, celecoxib, propafenon and difenhydramine. When treatment with these drugs is initiated the dose of Betaloc ZOK might have to be reduced for patients treated with Betaloc ZOK.

The following combinations with Betaloc ZOK should be avoided:

Barbituric acid derivatives: Barbiturates (investigated for pentobarbital) induce the metabolism of metoprolol by enzyme induction.

Propafenone: Upon administration of propafenone to four patients on metoprolol therapy, the plasma concentrations of metoprolol increased 2-5 fold and two patients experienced side-effects typical of metoprolol. The interaction was confirmed in eight healthy volunteers. The interaction is probably explained by the fact that propafenone, similarly to quinidine, inhibits the metabolism of metaprolol via cytochrome P450 2D6. The combination is probably difficult to handle since propafenone also has beta- receptor blocking properties.

Verapamil: In combination with beta-receptor blocking drugs (described for atenolol, propranolol and pindolol) verapamil may cause bradycardia and fall in blood pressure. Verapamil and beta-blockers have additive inhibitory effects on AV-conduction and sinusnode function.

The following combinations with Betaloc ZOK may require modified drug dosage:
Amiodarone: A case report suggests that patients treated with amiodarone may develop pronounced sinus bradycardia when treated simultaneously with metoprolol. Amiodarone has extremely long half-life(around 50 days), which implies that interactions can occur for a long time after withdrawal of the drug.

Antiarrhythmics, class I and III antiarrhythmics and beta-receptor blocking drugs have additive

negative inotropic effects which may result in serious haemodynamic side effects in patients with impaired left ventricular function. The combination should also be avoided in “sick sinus syndrome” and pathological AV-conduction. The interaction is best documented for disopyramide.

Non-steroidal anti-inflammatory/antirheumatic drugs: NSAID-antiphlogistics have been shown to counteract the antihypertensive effect of beta-receptor blocking drugs. Primarily, indomethacin has been studied. This interaction probably does not occur with sulindac. A negative interaction study on diclofenachas been performed.

Digitalis glycosides: digitalis glycosides in association with β-blockers, may increase atrioventricular conduction time and may induce bradycardia.

Diphenhydramin: Diphenhydramin decreases (2.5 times) clearance of metoprolol to alpha-hydroximetoprolol via CYP 2D6 in fast hydroxylating persons. The effects of metoprolol are enhanced.

Diltiazem: Diltiazem and beta-receptor blockers have additive inhibitory effects on the AV-conduction andsinusnode function. Pronounced bradycardia has been observed (case reports) during combination treatmentwith diltiazem.

Epinephrine: There are about ten reports on patients treated with nonselective beta-receptor blockers (including pindolol and propranolol) that developed pronounced hypertension and bradycardia afteradministration of epinephrine (adrenaline). These clinical observations have been confirmed in studies in healthy volunteers. It has also been suggested that epinephrine in local anestethics may provoke these reactions upon intravasal administration. The risk is probably less with cardioselective beta-receptor blockers.

Phenylpropanolamine: Phenylpropanolamine (norephedrine) in single doses of 50 mg may increase the diastolic blood pressure to pathological values in healthy volunteers. Propranolol generally counteracts therise in blood pressure induced by phenylpropanolamine. However, beta-receptor blockers may provoke paradoxical hypertensive reactions in patients who take high doses of phenylpropranolamine. Hypertensive crises during treatment with only phenylpropanolamine have been described in a couple of cases.

Quinidine: Quinidine inhibits the metabolism of metoprolol in so-called rapid hydroxylators (more than 90% in Sweden) with markedly elevated plasma levels and enhanced beta-

blockade as a result. A corresponding interaction might occur with other beta-blockers metabolised by the same enzyme (cytochrome P450 2D6).

Clonidine: The hypertensive reaction when clonidine is suddenly withdrawn may be potentiated by beta- blockers. If concomitant treatment with clonidine is to be discontinued, the beta-blocker medication should be withdrawn several days before clonidine.

Rifampicin: Rifampicin may induce the metabolism of metoprolol resulting in decreased plasma levels.

Patients receiving concomitant treatment with other beta-blockers (i.e. eye drops) or MAO-inhibitors should be kept under close surveillance. In patients receiving beta-receptor blocker therapy, inhalation anaesthetics enhance the cardio-depressant effect. The dosages of oral antidiabetics may have to be readjusted in patients receiving beta-blockers. The plasma concentration of metoprolol can increase when cimetidine or hydralazine are administered simultaneously.

Fertility, pregnancy and lactation

Pregnancy

Betaloc ZOK should only be given during pregnancy and lactation when use is considered essential. In general, β-blockers reduce placental perfusion, which has been associated with growth retardation, intrauterine death, abortion and early labour. It is therefore suggested that appropriate maternofetal monitoring be performed in pregnant women treated with metoprolol. Beta-receptor blockers may cause bradycardia in the foetus and in the new-born infant. This should be considered if these drugs are prescribed in the last trimester and in association with delivery. Betaloc ZOK should gradually be withdrawn 48-72 hours before planned childbirth. If this is not possible the newborn infant should be supervised during 48-72 hours postpartum for signs and symptoms of beta-blockade (e.g. heart- and lung complications).

Lactation

Metoprolol is concentrated in human breast milk in a quantity that corresponds to approximately three times the quantity found in the plasma of the mother. The risk for harmful reactions with respect to the breastfeeding child seems to be low at therapeutic doses of the medicine. The breast-feeding child should however be observed regarding signs of betablockade.

Effect on ability to drive and use machines

As dizziness and fatigue may occur in Betaloc ZOK treatment, this should be considered when strict attention is required, e.g. when driving or operating machines.

Undesirable effects

Adverse reactions occur in approximately 10% of the patients and they are usually dose-related. Adverse reactions, related to metoprolol are presented below according to organ class and frequency. The frequencies are defined as following: very common (≥1/10), common (≥1/100, <1/10), less common (≥1/1000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000) and frequency unknown (cannot be calculated from available data)

Blood and lymphatic system

Rare	Thrombocytopenia

Psychiatric disorders

Less common	Depression, nightmares, sleeping disturbance
Rare	Memory impairment, confusion, hallucinations,nervousness, anxiety
Frequency unknown	Impaired concentration ability

Central and peripheral nervous system

Very common	Fatigue
Common	Dizziness, headache
Less common	Paraesthesiae
Rare	Taste disturbances
Frequency unknown	Muscular cramps

Eyes

Rare	Visual disturbances, dry and/or irritated eyes
Unknown frequency	Conjunctivitis-like symptoms

Ears and balance organ

Rare	Tinnitus

Heart

Common	Peripheral coldness in extremities, bradycardia,palpitations
Less common	Transient aggravation of heart failure, cardiogenicshock in patients with acute myocardial infarction
Rare	Prolonged AV-conduction time, cardiac arrhythmias
Frequency unknown	Gangrene in patients with severe peripheral vasculardisorders

Respiratory

Common	Shortness of breath when physically active
Less common	Bronchospasm in patients with bronchial asthma orasthmatic problems
Frequency unknown	Rhinitis

Gastrointestinal

Common	Abdominal pain, nausea, vomiting, diarrhoea,constipation
Frequency unknown	Dry mouth

Liver and biliary tracts

Rare	Elevated transaminases
Frequency unknown	Hepatitis

Skin and subcutaneous tissue

Less common	Hypersensitivity reactions in the skin
Rare	Aggravated psoriasis, photosensitivity

		reactions,hyperhidrosis, hair loss
Musculoskeletal system and connective tissue		
	Frequency unknown	Arthralgia
Reproductive organs and mammary glands		
	Rare	Reversible libido dysfunction
	General	
	Less common	Chest pain, oedema, weight gain

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important.

It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions at:

Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Telepon: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

Overdose

Toxicity

7.5 g to an adult caused lethal intoxication. 100 mg to a 5-year old gave no symptoms after gastric lavage.450 mg to a 12-year old and 1.4 g to an adult gave moderate intoxication, 2.5 g to an adult caused serious intoxication, and 7.5 g to an adult gave very serious intoxication.

Symptom

Cardiovascular symptoms are most important, but in some cases, especially in children and youngindividuals, CNS symptoms and respiratory depression may dominate. Bradycardia, AV-

block I-III, QT- prolongation (exceptional cases), asystole, fall in blood pressure, poor peripheral perfusion, cardiac insufficiency, cardiogenic shock. Respiratory depression, apnoea. Others: Fatigue, confusion, unconsciousness, fine tremor, cramps, perspiration, paraesthesiae, bronchospasm, nausea, vomiting, possibly oesophageal spasm, hypoglycaemia (especially in children) or hyperglycaemia, hyperkalaemia. Effect on the kidneys. Transient myasthenic syndrome. Concomitant ingestion of alcohol antihypertensives, quinidine or barbiturates may aggravate the patient's condition. The first signs of overdosing may be seen20 minutes to 2 hours after ingestion.

Management

Care should be provided at a unit that can offer suitable support measures, monitoring and supervision.If justified, gastric lavage and/or activated charcoal can be used.
Atropine, adrenoceptor stimulant or pacemaker for treatment of bradycardia and conduction disorders.

Intubation and mechanical ventilation should be done with very broad indication. Pacemaker is option. Withcirculatory arrest in connection with overdose, resuscitation measures for several hours may be warranted.

Hypotension, acute myocardial infarction and shock should be treated with appropriate volume expansion,administration of glucagon (followed by intravenous infusion of glucagon if necessary), intravenous administration of an adrenoceptor stimulant, such as dobutamine, with the addition of α_1 receptor agonists upon vasodilation. Intravenous use of Ca^{2+} may also be considered.

Bronchospasm can usually be reversed through bronchodilators.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Beta-receptor blocker,
selectiveATC code: C07A B02

Metoprolol is a $beta_1$-selective receptor blocker, i.e. metoprolol affects the $beta_1$-receptors of the heart in lower doses than needed to affect beta2-receptors in peripheral vessels and bronchi. The selectivity for Betaloc ZOK is dose dependent, but, as the peak plasma

concentration for this dosage form is significantly lower compared to the same dose given as ordinary tablets, a higher degree of beta$_1$-selectivity is obtained with the ZOC-dosage form. Metoprolol has no beta-stimulating effect and has little membrane- stimulating effect. Beta-receptor blockers have negative inotropic and chronotropic effect.

Metoprolol therapy reduces the effect of catecholamines in association with physical and psychic strain and gives lower heart rate, cardiac output and blood pressure. In stress situations with an increased release of adrenaline from the adrenal glands, metoprolol does not prevent the normal physiological vascular dilation. In therapeutic doses, metoprolol has less contractile effect on the bronchial muscles than non- selective beta-blockers. This property enables treatment of patients with bronchial asthma or other pronounced obstructive lung diseases with metoprolol in combination with beta$_2$-receptor stimulants. Metoprolol influences insulin release and carbohydrate metabolism to less extent than non-selective beta-blockers and therefore it can also be given to patients with diabetes mellitus. The cardiovascular reaction in hypoglycaemia, e.g. tachycardia, is less influenced by metoprolol and the return of blood sugar level to normal is faster than for non-selective beta-receptor blockers.

In hypertension, Betaloc ZOK lowers the blood pressure significantly for more than 24 hours both in lying and standing position as well as during exercise. In treatment with metoprolol an increase in the peripheral vascular resistance is observed initially. In long-term treatment, however, the obtained lowering in blood pressure may be due to reduced peripheral vascular resistance and unchanged cardiac output.

Paediatric population

In a four-week study with 144 patients between 6 and 16 years old with essential hypertension, doses of 1.0 and 2.0 mg/kg of Betaloc ZOK decreased placebo-corrected systolic blood pressure by 4-6 mmHg. Diastolic blood pressure showed a placebo-corrected decrease for the higher dose with 5 mmHg and a dose-dependent decrease for 0.2, 1.0 and 2.0 mg/kg. No noticeable differences between ages, Tanner scale (adolescent physical development) or race.

Metoprolol reduces the risk of cardiovascular-related deaths in men with moderate/serious hypertension. There is no disturbance in the electrolyte balance.

Effect in chronic heart failure

In the MERIT-HF (Metoprolol CR/XL Randomized Intervention Trial in Congestion Heart Failure) study treatment with metoprolol CR added to standard treatment with ACE inhibitors and diuretics in patients with decreased LVEF and symptoms of mild to severe chronic heart failure reduced:

- All cause mortality by 34% (p=0.0062 (adjusted); p=0.00009 (nominal))
- Combined endpoint of all cause mortality, and all cause hospitalisation (time to first event) by 19% (p=0.00012)
- Combined endpoint of all cause mortality, and hospitalisation due to worsening heart failure (time to first event) by 31% (p=<0.00001)
- Combined endpoint of death and heart transplantation (time to first event) by 32% (p=0.0002)
- Cardiovascular death by 38% (p=0.00003)
- Sudden death by 41% (p=0.0002)
- Death from worsening heart failure by 49% (p=0.0023)
- The pooled incidence of cardiac death and non-fatal acute MI by 39% (p=<0.00001)
- Combined endpoint of all cause mortality, hospitalisation due to worsening heart failure, and emergency room (ER) visit due to worsening heart failure (time to first event) by 32% (p=<0.00001)
- The number of hospitalisations due to worsening heart failure by 30% and the number of hospitalisations due to cardiovascular (CV) causes by 15% (p=0.0003).

In tachyarrhythmias the effect of increased sympatholytic activity is blocked, and this gives a lower heart rate primarily by reduced automatisation in the pacemaker cells, but also through a prolonged supraventricular conduction time. Metoprolol reduces the risk of reinfarction and cardiac death, especiallysudden death after myocardial infarction.

Pharmacokinetic properties

The Betaloc ZOK prolonged release tablet consists of micro-encapsulated beads of metoprolol succinate, and each bead is a separate depot unit. Each bead is coated with a polymeric membrane, which controls therate of drug release. The tablet disintegrates rapidly in contact with fluid whereby the beads are dispersed over a large surface in the gastrointestinal tract. The release is independent of the pH of the surrounding fluid and goes on with an almost constant rate for about 20 hours. The dosage form gives an even plasma concentration and effect duration over 24 hours.

The absorption is complete after oral administration and the substance is absorbed along the whole gastrointestinal tract, also in colon. The bioavailability of Betaloc ZOK is 30-40%.

Metoprolol is metabolised in the liver mainly by CYP2D6. Three main metabolites have been identified, though none has a beta-blocking effect of clinical importance. Metoprolol is excreted to approximately 5% in unchanged form via the kidneys, the remaining dose as metabolites.

The pharmacokinetics of metoprolol in children and young adults, 6 – 17 years, resembles that of adults. Clearance of orally given metoprolol (CL/F) increased with linear relation to the bodyweight.

Preclinical safety data

Metoprolol has been tested clinically to a very large extent. Relevant information for the prescriber can befound in other parts of the Summary of Product Characteristics.

PHARMACEUTICAL PARTICULARS

List of excipients

Ethylcellulose, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, paraffin, macrogol,anhydrous non-colloidal silicon dioxide,sodium stearyl fumarate, titanium dioxide (E 171).

Incompatibilities

Not applicable.

Shelf life

3 years.

Special precautions for storage

Do not store above 30°C

Pack Size

25 mg Betaloc Zok tablet : Box of 2 Blister @ 14 Prolonged release tablets(Reg. No : DKI2151304214A1)
50 mg Betaloc Zok tablet : Box of 2 Blister @ 14 Prolonged release tablets(Reg. No. : DKI2151304214B1)

Golongan Obat Keras

HARUS DENGAN RESEP DOKTER

Special precautions for disposal

Not applicable.

Manufactured and Packed by AstraZeneca AB, Gartunavagen SE-152 57, Södertälje Sweden

Imported by

PT AstraZeneca
Indonesia Cikarang,
Bekasi – Indonesia

Date of revision of text **: 26 March 2025**

Document Number :VV-RIM-07103754

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DISETUJUI OLEH BPOM : 22/7/2025

ID: EREG100422VR12400222
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Proposed packaging material		
Code	Betaloc Zok-PIL-03.02	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: RO-Change Event-0042096	
Code of previous version	N/A	
Changes	Postal Code Changes and Revision of PIL to Align with Product Information	
Reference	☐CDS version: ☒CPIL version: Refer to Sweden PIL	☐SmPC country/version/date: ☐GRL approval:
Name & Date	ROM (08 July 2025)	

Informasi untuk Pasien

BETALOC® ZOK 25 & 50 mg

Tablet Pelepasan Lambat

Metoprolol Succinate

Bacalah seluruh isi leaflet ini dengan seksama sebelum anda mulai menggunakan obat ini karena leaflet ini berisi informasi penting bagi anda.

- Simpan leaflet ini, anda mungkin memerlukannya di kemudian hari.
- Apabila anda memiliki pertanyaan lebih lanjut, hubungi dokter, apoteker, atau perawat anda.
- Obat ini hanya diresepkan untuk anda. Dilarang memberikan obat ini untuk orang lain. Hal ini dapat membahayakan orang lain, bahkan jika tanda penyakit yang mereka derita sama dengan penyakit anda.
- Apabila anda mengalami efek samping, komunikasikan dengan dokter, apoteker atau perawat anda. Hal ini termasuk efek samping yang mungkin timbul yang tidak terdaftar dalam leaflet ini.

Informasi yang terkandung dalam leaflet ini:

1. Betaloc Zok dan kegunaannya
2. Hal yang perlu Anda ketahui sebelum mengkonsumsi Betaloc Zok
3. Cara pemakaian Betaloc Zok
4. Efek samping yang mungkin terjadi
5. Cara penyimpanan Betaloc Zok
6. Isi kemasan obat dan informasi lainnya

1. Betaloc Zok dan kegunaannya

Betaloc Zok mengandung zat aktif Metoprolol Succinate, yang tergolong dalam kelompok obat antihipertensi oral.

Betaloc Zok digunakan untuk mengobati tekanan darah tinggi, angina pectoris, gagal jantung dan terapi pemeliharaan setelah infark miokard

2. Hal yang perlu Anda ketahui sebelum mengkonsumsi Betaloc Zok

Jangan gunakan Betaloc Zok :

- Apabila anda memiliki alergi terhadap Metoprolol Succinate atau bahan lain yang terkandung dalam obat ini (*lihat bagian isi kemasan obat dan informasi lainnya*).
- Apabila anda memiliki reaksi alergi berat terhadap obat-obatan lain dalam jenis yang sama untuk mengontrol kadar gula darah anda.
- Apabila anda memiliki penyumbatan jantung yang parah dan/atau detak jantung yang lambat.
- Apabila anda memiliki tekanan darah yang sangat rendah.

Peringatan dan pencegahan

Komunikasikan terhadap dokter atau apoteker anda sebelum menggunakan Betaloc Zok apabila:

- Apabila menggunakan verapamil. Betaloc Zok tidak dapat diberikan kepada pasien yang menggunakan verapamil.
- Apabila anda mengidap penyakit asma dan sedang menjalankan terapi dengan beta-agonis.
- Selama pengobatan dengan Betaloc Zok, risiko gangguan metabolisme karbohidrat cenderung lebih rendah dibandingkan selama pengobatan dengan formulasi tablet konvensional β1-selective blocker dan jauh lebih sedikit dibandingkan dengan β-blocker non-selektif.
- Gangguan konduksi A-V yang sudah ada sebelumnya dengan derajat sedang dapat menjadi memperburuk kondisi anda, tetapi kondisi ini jarang terjadi.
- Jika anda mengalami peningkatan bradikardia, Betaloc Zok harus diberikan dalam dosis yang lebih rendah atau secara bertahap diturunkan.
- Betaloc Zok dapat memperburuk gejala gangguan sirkulasi arteri perifer anda.

DISETUJUI OLEH BPOM : 22/7/2025

ID: EREG100422VR12400222
EREG100422VR12400221

- Apabila anda mengalami gangguan hati sedang atau berat. Apabila anda mengalami gangguan hati berat, maka Betaloc Zok tidak direkomendasikan bagi anda.
- Apabila anda memiliki phaeochromocytoma, maka penggunaan alfa-blocker harus dipertimbangkan
- Pemberhentian beta-blocker secara tiba-tiba sangat berbahaya, berisiko tinggi untuk anda dan akan memperburuk kondisi jantung.
- Pemberhentian penggunaan Betaloc Zok tidak direkomendasikan bagi anda yang akan menjalani operasi.

Anak-anak dan remaja

Betaloc Zok tidak direkomendasikan untuk anak dan remaja di bawah usia 18 tahun. Keamanan dan keefektifan obat ini pada anak-anak dan remaja di bawah usia 18 tahun tidak diketahui.

Betaloc Zok dan obat-obatan lain

Komunikasikan kepada dokter atau apoteker anda apabila anda sedang, pernah, atau akan mengkonsumsi obat-obatan lain.

Secara khusus, anda harus memberitahukan dokter anda apabila anda sedang mengkonsumsi obat-obatan yang mengandung bahan aktif sebagai berikut

- Carbamazepine, phenobarbital, phenytoin. Obat-obatan ini digunakan untuk mengendalikan kejang/ayan atau nyeri kronis
- Quinidine, terbinafine, paroxetine, fluoxetine, sertraline, celecoxib, propafenon and difenhydramine. Obat-obatan sebagai penghambat CYP2D6
- Verapamil. Obat ini untuk mengobati jantung dan aritmia
- Amiodarone. Salah satu anti aritmia untuk mengobati gangguan jantung
- Anti aritmia kelas I, seperti: quinidine, hydroquinidine, disopyramide
- Non-Steroidal Anti Inflammatory Drugs, seperti: ibuprofen, aspirin, asam mefenamat
- Digitalis glycosides. Sebagai obat untuk jantung
- Diphenhydramine. Obat ini sebagai anti histamin untuk meredakan alergi
- Epinephrine. Merupakan obat untuk meningkatkan hormone adrenalin
- Phenylpropanolamine, obat ini merupakan dekongestan untuk meredakan flu
- Clonidine. Merupakan obat untuk menurunkan tekanan darah
- Rifampicin - obat antibiotik ini digunakan untuk mengobati infeksi seperti tuberculosis
- Diltiazem – obat ini digunakan untuk mengobati tekanan darah tinggi

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Kehamilan dan menyusui

Bicarakan dengan dokter anda sebelum mengkonsumsi Betaloc Zok apabila anda sedang hamil atau berencana untuk hamil.

Bicarakan dengan dokter anda apabila anda berencana menyusui selama mengkonsumsi Betaloc Zok. Betaloc Zok sebaiknya tidak digunakan selama menyusui atau apabila memiliki rencana untuk menyusui.

Mengemudi dan penggunaan mesin

Apabila anda merasa pusing dan lesu setelah mengkonsumsi Betaloc Zok, jangan mengemudi atau menggunakan mesin.

3. Cara menggunakan Betaloc Zok

Selalu gunakan obat ini persis seperti yang diinstruksikan dokter anda. Apabila anda tidak yakin, periksa ulang dengan dokter, apoteker, atau perawat anda.

Dosis Betaloc Zok yang direkomendasikan adalah 25-200 mg sekali sehari. Dosis awal Betaloc Zok dengan kombinasi obat lain untuk gagal jantung yang stabil adalah 12.5-25 mg sekali sehari dan ditingkatkan sesuai kebutuhan dengan dosis maksimal yaitu 200 mg sekali sehari.

Dokter anda dapat meresepkan Betaloc Zok untuk mengatasi hipertensi, angina pectoris, dan terapi pemeliharaan setelah infark miokard

Cara menggunakan Betaloc Zok

Tablet dapat dipotong, namun tablet tidak boleh dipecah maupun dikunyah. Telan tablet dalam keadaan utuh dengan air. Anda dapat meminum tablet ini dengan atau tanpa makanan. Tablet diminum sekali sehari, sebaiknya pada pagi hari. Usahakan untuk meminum tablet pada waktu yang sama setiap harinya. Hal ini akan memudahkan anda mengingat minum obat.

Apabila anda menggunakan Betaloc Zok dalam jumlah lebih dari yang seharusnya

Apabila anda mengkonsumsi lebih banyak tablet Betaloc Zok dari yang seharusnya, segera bicarakan dengan dokter anda.

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Apabila anda lupa menggunakan Betaloc Zok

- Apabila anda lupa mengkonsumsi Betaloc Zok, minumlah segera setelah anda ingat. Meskipun demikian, apabila sudah mendekati waktu untuk minum dosis berikutnya, loncati dosis yang terlupa.

Apabila anda berhenti menggunakan Betaloc Zok

Teruskan penggunaan Betaloc Zok sampai dokter anda mengatakan untuk berhenti. Hal ini bertujuan untuk menjaga tekanan darah anda.

Apabila anda memiliki pertanyaan lebih lanjut mengenai penggunaan obat ini, tanyakan pada dokter atau apoteker anda.

4. Efek samping yang mungkin terjadi

Seperti pada obat-obatan lainnya, obat ini dapat mengakibatkan efek samping, meskipun tidak semua orang mengalaminya.

Beberapa gejala memerlukan perhatian medis segera:

Anda harus berhenti menggunakan Betaloc Zok dan menemui dokter anda segera apabila anda mengalami gejala tekanan darah rendah berikut ini: pusing, mual, muntah, lemas, pandangan buram, konsentrasi berkurang, dan tubuh terasa tidak stabil.

- Sangat umum (dapat mempengaruhi hingga 1 dari 10 orang): kelelahan
- Umum (dapat mempengaruhi hingga 1 dari 100 orang): Pusing, sakit kepala, rasa dingin (kedinginan) pada anggota gerak, detak jantung lebih lambat atau lebih cepat dari biasanya, nafas yang terasa sesak saat beraktifitas fisik, nyeri perut, mual, muntah, diare, konstipasi
- Kurang umum (dapat mempengaruhi hingga 1 dari 1000 orang): Depresi, mimpi buruk, gangguan tidur, kesemutan pada bagian tubuh tertentu, perburukan kondisi gagal jantung sementara, syok kardiogenik pada pasien dengan infark miokard akut, bronkospasme pada pasien dengan asma bronkial atau masalah asma, reaksi hipersensitivitas pada kulit, nyeri dada, edema, dan penambahan berat badan
- Jarang (dapat mempengaruhi hingga 1 dari 10000 orang): Trombositopenia, gangguan ingatan, kebingungan, halusinasi, gugup, cemas, gangguan pengecapan, gangguan penglihatan, mata kering dan/atau iritasi, tinitus, perpanjangan waktu konduksi-AV,

aritmia jantung, peningkatan transaminase, psoriasis yang lebih parah, reaksi fotosensitifitas, hiperhidrosis, rambut rontok , gangguan libido reversible

- Tidak diketahui: Gangguan kemampuan konsentrasi, kram otot, gejala mirip konjungtivitis, gangren pada pasien dengan gangguan pembuluh darah perifer yang parah, rhinitis, mulut kering, hepatitis, arthralgia

Pelaporan efek samping

Apabila anda mengalami efek samping, hubungi dokter, apoteker, atau perawat anda. Hal ini termasuk efek samping yang mungkin terjadi yang tidak disebutkan dalam leaflet ini. Anda juga dapat melaporkan efek samping secara langsung ke kontak industri farmasi pada bagian "Informasi Lebih Lanjut". Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. Cara penyimpanan Betaloc Zok

Jauhkan obat ini dari penglihatan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah lewat tanggal kadaluwarsa yang dapat dilihat pada blister atau karton setelah tanda 'EXP'. Tanggal kadaluwarsa disini mengacu pada tanggal terakhir bulan yang tercantum.

Simpan obat pada suhu kamar (dibawah 30°C)

Jangan gunakan obat ini jika kemasan dalam keadaan rusak atau adanya tanda – tanda kerusakan.

Jangan membuang obat ini pada saluran pembuangan air atau tempat sampah rumah tangga. **Mintalah petunjuk dari apoteker tentang tata cara pembuangan sisa obat yang sudah tidak digunakan**. Hal ini dapat membantu melindungi lingkungan hidup.

Komposisi bahan tambahan

Ethylcellulose, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, paraffin, macrogol,anhydrous non-colloidal silicon dioxide,sodium stearyl fumarate, titanium dioxide (E 171).

Golongan Obat Keras
HARUS DENGAN RESEP DOKTER

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