PACKAGE LEAFLET: Information for the patient

METOPROLOL

Film-coated tablets – 50 mg

(Metoprolol tartrate)

Read all of this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT METOPROLOL IS AND WHAT IT IS USED FOR

Metoprolol belongs to a group of drugs called cardioselective beta-blockers. It reduces cardiac contraction and decreases the heart rate.

Metoprolol is used in adults:

- to treat high blood pressure (either alone or combined with other medications that lower blood pressure, for example, diuretics, peripheral vasodilators, or ACE inhibitors);
- to prevent chest pain caused by reduced oxygen supply to the heart (angina pectoris). To relieve acute seizures, your doctor may prescribe nitroglycerin if necessary;
- in the established or suspected heart attack;

- in prevention after heart attack;
- in disorders of heart function manifested by palpitations (sensation of feeling the beating of the heart);
- to prevent headaches (migraines).

See your doctor if you do not feel better or feel worse.

2. BEFORE YOU TAKE METOPROLOL

Do not take Metoprolol if you:

- are hypersensitive (allergic) to metoprolol tartrate, other beta-blockers or to any of the excipients of the drug;
- suffer from blockage in the electrical conduction of the heart (second- and third-degree atrioventricular blockade degree);
- suffer from decompensated heart failure, a serious heart disease;
- suffer from a reduction in heart rate, that is, the number of heartbeats per minute (less than 45-50 beats);
- suffer from a heart disease called “sinus node syndrome” (characterized by disturbances of the rhythm of the heart);
- suffer from severe blood circulation disorders (peripheral arterial circulation);
- suffer from decreased blood pressure with severe reduction in heart function (cardiogenic shock);
- have an untreated tumor of the adrenal gland, a gland located above the kidney that can cause an elevation of blood pressure (pheochromocytoma);
- suffer from low blood pressure;
- suffer from severe bronchial asthma or have a history of severe bronchial narrowing that makes it difficult to breathe;
- have recently had a heart attack or severe heart failure.

Take special care with Metoprolol

Ask your doctor or pharmacist before taking Metoprolol.

Tell your doctor if you suffer or have suffered from the following disorders:

- respiratory diseases of mild to moderate severity (bronchospastic diseases). Metoprolol should be administered at the lowest effective dose and always simultaneously with a β2-agonist (see "Do not take Metoprolol").
- high blood sugar levels (diabetes), especially if you are being treated with insulin or medications that lower blood sugar levels by mouth (see section "Other Medications and Metoprolol"), because this medication may not make you recognize the symptoms of hypoglycemia (low blood sugar) such as rapid heartbeat, dizziness and sweating;
- congestive heart failure, a disease of the heart;
- disorders of electrical conduction of the heart (first-degree atrioventricular block);
- heart attack;
- circulation disorders of the arms and legs (e.g., Raynaud's disease or phenomenon, intermittent claudication);
- if you have a known or suspected tumor of the adrenal gland, a gland located above the kidney that can cause an elevation of blood pressure (pheochromocytoma), Metoprolol should be always administered at the same time as an alpha blocker and only after treatment with the alpha blocker has been started (see "Do not take Metoprolol");
- a type of angina (chest pain) called Prinzmetal's angina;
- an increase in the function of a gland called the thyroid gland (thyrotoxicosis);
- allergy. If you have allergy and take beta-blockers, allergic reactions may be more severe than normal;
- liver problems (liver dysfunction) as the doctor may decide to change the dose.

If, during treatment with Metoprolol, you experience any undesirable eye effects (dry eyes and/or, occasionally, eruptions of the skin under the eye), consult your doctor immediately, who may decide to discontinue treatment (see section "Possible side effects").

If you have to undergo surgery that requires general anesthesia, inform the anesthesiologist (the doctor performing the anesthesia) that you are taking Metoprolol. The anesthesiologist will choose the most appropriate anesthetic for you in order to reduce any heart side effects during

anesthesia. Your doctor may decide to discontinue Metoprolol before surgery; in this case, the discontinuation is gradual and is completed about 48 hours before general anesthesia.

Elderly

If you are elderly, use this medication with caution. In fact, an excessive reduction in the blood pressure or heart rate may result in inadequate blood supply to the vital organs (see section 3 "How to take Metoprolol").

Children and adolescents

Efficacy and safety in children and adolescents younger than 18 years of age is limited, so Metoprolol is not recommended in this population (0-18 years).

Other medications and Metoprolol

Tell your doctor or pharmacist if you are taking or have recently taken any other medications.

Interactions with medications whose concomitant use is not recommended:

- medications to treat certain heart disorders belonging to the class of calcium antagonists (administered intravenously) such as verapamil and diltiazem. This association may potentiate the depressant effects of Metoprolol on the heart and blood pressure.

Interactions to consider:

- medications that lower blood pressure:
  - medicines that reduce levels of catecholamines in the blood (substances produced by the body that act by controlling the heart rate)
  - other beta-blockers (including in the form of eye drops), or monoamine oxidase (MAO) inhibitors, medicines used to treat depression, even in the 14 days following the discontinuation of treatment.
- medications to treat certain heart disorders belonging to the class of calcium antagonists (e.g., verapamil) by mouth
- medicines to treat heart rhythm abnormalities (antiarrhythmics such as quinidine, tocainide, procainamide, ajmaline, amiodarone, flecainide, disopyramide and propafenone)

- nitroglycerin, a medication used to treat angina
- medicines to induce anesthesia during surgical procedures (general and local anesthetics such as lidocaine) see also "Warnings and Precautions" section.
- medications to treat depression (fluvoxamine, fluoxetine, paroxetine, sertraline, bupropion, clomipramine, desipramine)
- medications to treat some disorders of the mind (antipsychotics such as chlorpromazine, fluphenazine, haloperidol, thioridazine)
- medicines used to treat HIV, (antiretrovirals such as ritonavir)
- medicines to treat allergies (antihistamines such as diphenhydramine)
- medicines to treat malaria (hydroxychloroquine or quinidine)
- medicines to treat fungal infections (antifungals such as terbinafine)
- hydralazine and prazosin (medicines used to treat high blood pressure)
- medicines to treat some heart disorders belonging to the class of digitalic glycosides.
- medicines used to treat some respiratory problems (such as asthma and cough) or to clear the nose (nasal drops) or to treat some eye disorders (ophthalmic drops) for example: adrenaline, noradrenaline, isoprenaline, ephedrine, phenylephrine, phenylpropanolamine, xanthine derivatives
- medicines to treat inflammation and pain (nonsteroidal anti-inflammatory drugs)
- rifampin, an antibiotic
- medicines that belong to the alpha-adrenergic blocker class (guanethidine, betanidine, reserpine, alpha-methyldopa or clonidine), used to treat diseases such as benign prostatic hypertrophy (enlargement of the prostate), urinary retention (inability of the bladder to empty completely) and high blood pressure
- medicines to reduce blood sugar levels (antidiabetics and insulin)
- medicines used to treat migraines (ergot alkaloids)
- dipyridamole. In general, the administration of a beta-blocker should be discontinued before a dipyridamole test, carefully monitoring heart rate after injection of dipyridamole.

Taking Metoprolol with food and drinks

Alcohol may interact with Metoprolol by increasing the hypotensive effect, therefore it should not be consumed during the time of treatment.

Pregnancy and breastfeeding

If you are pregnant, if you suspect or plan to become pregnant, or if you are breastfeeding, see your doctor or pharmacist before starting treatment with this medicine.

Pregnancy

Metoprolol should not be taken during pregnancy, except for cases when the doctor considers it necessary. In case of treatment with Metoprolol during pregnancy, your doctor will prescribe the lowest dose possible and will ask you to discontinue therapy at least 2 to 3 days before delivery to avoid effects in the unborn child (e.g., bradycardia, hypoglycemia).

Breastfeeding

Metoprolol passes into the breast milk and for this reason it should not be taken during breastfeeding.

Driving and using machines

Dizziness, fatigue or visual disturbances may occur while taking Metoprolol. If this occurs, do not drive or use any tools or machinery.

Important information about some of the excipients of Metoprolol

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
Metoprolol contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. HOW TO TAKE METOPROLOL

Always take Metoprolol only as your doctor has told you. Talk to your doctor if you are not sure. If you feel that the effects of Metoprolol are too strong or too weak, talk to your doctor or pharmacist.
Always take the tablets with a glass of water and without chewing.

Take Metoprolol regularly with respect to meals. If your doctor has advised you to take Metoprolol either before breakfast or during breakfast, continue taking Metoprolol on the same schedule for the entire duration of treatment.

To treat high blood pressure:
The initial dose is 100 mg daily, as a single dose or divided twice daily. The dose may be increased every week according to the response, up to 400 mg daily. The maintenance dose is 100 - 200 mg daily.

To prevent chest pain caused by reduced oxygen supply to the heart (angina pectoris):
50 - 100 mg two or three times daily.

Heart attack:
50 mg metoprolol tartrate every six hours. The usual maintenance dose is 200 mg daily in divided doses. The medicine should be taken for at least 3 months.

In disorders of heart function manifested by palpitations (sensation of feeling the heartbeat):
50 mg two or three times daily, which may be increased if necessary up to 300 mg daily in divided doses.

Prevention of headaches (migraine):
100 - 200 mg daily in divided doses (in the morning and evening).

Use in patients with reduced liver function
If you have impaired liver function, your doctor will prescribe Metoprolol starting with low doses and will increase the dosage cautiously based on your response to the medication.

Elderly (> 65 years old)

If you are over 65 years old, this medication will be prescribed with caution because of the increased likelihood of undesirable effects. In particular, your doctor will regularly check your blood pressure, and the frequency of your heartbeat (see "Warnings and Precautions").

Use in children and adolescents

The use of this medication is not recommended in children and adolescents younger than 18 years of age.

If you take more Metoprolol than you should

If you take more Metoprolol than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

While waiting for medical attention, within 4 hours after ingestion, it may be helpful to induce vomiting and/or take activated charcoal to remove the medication from the stomach and intestines.

In any case after excessive intake of beta-blockers should always be kept under control at the hospital.

An overdose of this medicine may cause the following symptoms:

- excessive reduction in blood pressure
- reduction in the number of heartbeats (sinus bradycardia)
- difficulty of the heart to pump blood to the body due to alteration of the electrical conduction system of the heart (atrioventricular block)
- severe heart disease (heart failure)
- decreased blood pressure with severe reduction in heart function (shock cardiogenic)
- cardiac arrest
- narrowing of the bronchi and difficulty breathing (bronchospasm)
- deterioration of consciousness (or even coma)
- seizures
- nausea
- vomiting

- bluish discoloration of the body (cyanosis)
- death.

Simultaneous intake of alcohol, medication to lower blood pressure, quinidine (medication to treat heart rhythm disturbances), or barbiturates (medication to treat epilepsy) aggravates signs and symptoms. The first manifestations upon excessive intake of the medication occur 20 minutes to 2 hours after taking the medicine. The effects may also persist for several days.

If you forget to take Metoprolol

If you forget to take one dose (or more), take the next dose in its usual time.
Do not take a double dose (or higher) to make up a forgotten dose (doses).

If you stop taking Metoprolol

Do not stop the treatment with Metoprolol abruptly, especially if you have disease due to reduced oxygen supply to the heart (ischemic disease), such as angina pectoris (chest pain). To prevent worsening of angina pectoris, your doctor will reduce your dosage gradually over a period of 1-3 weeks and, if necessary, prescribe replacement therapy.
During the discontinuation of treatment, the doctor will keep you under close surveillance.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all drugs, Metoprolol may cause side effects, although not everybody gets them.
Stop the treatment and inform your doctor straight away, if any of the following side effects appears to you:

- allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives);
- eye side effects (dry eyes and/or occasionally eruptions of the skin under the eye).

In addition, the following side effects may manifest:

Common (may affect up to 1 in 10 people)

- headache
- dizziness
- tiredness
- slow heartbeat (bradycardia)
- low blood pressure which might make you faint (syncope) or dizzy
- feeling short of breath when exercising
- nausea
- vomiting
- abdominal ache.

Rare (may affect up to 1 in 1,000 people)

- diarrhea
- constipation
- skin rashes (in the form of hives, skin lesions)
- muscle cramps
- bronchospasm (even if you have not suffered from obstructive lung disease in the past)
- swelling (edema)
- pain in the fingers and toes that first turn whitish then bluish and finally reddish (Raynaud's phenomenon)
- heart disease (heart failure)
- alterations in the rhythm of the heart
- perception of feeling the beating of the heart (palpitations)
- reduced level of consciousness
- drowsiness or insomnia
- tingling in the arms and legs (paresthesias)
- depression
- nightmares.

Very rare (may affect up to 1 in 10,000 people)

- weight gain
- abnormalities in liver function tests
- erectile dysfunction
- disorders of sexual desire
- La Peyronie's disease (disease of the penis)
- inflammation of the joints (arthritis)
- reactions of sensitivity to light (photosensitivity)
- excessive sweating
- hair loss (alopecia)
- worsening of psoriasis (skin disease)
- severe liver disease (hepatitis)
- dryness of the mucosa of the mouth
- retroperitoneal fibrosis (inflammation of the abdomen)
- irritation and inflammation of the mucous membrane of the nose (rhinitis)
- gangrene (bluish or greenish skin of the hands or feet) if you have severe disorders of the peripheral blood circulation
- reduction in the number of platelets in the blood (thrombocytopenia)
- personality disorders
- hallucinations
- decreased vision (e.g., blurred vision)
- irritation
- ringing in the ears (tinnitus)
- auditory disturbances if recommended doses are exceeded (e.g., reduced hearing or deafness)
- disturbances in the electrical conduction of the hear
- chest pain.

In addition, the following side effects may appear, the frequency of which cannot be determined:

Nervous system disorders

- confusional state

Metabolism and nutrition disorders

- increased triglycerides (fats) in the blood
- reduction of HDL cholesterol in the blood.

If any of the side effects gets worse or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE METOPROLOL

Keep out of the reach and sight of children!

Do not use the tablets after the expiry date which is stated on the package.

Do not store above 25°C!

Keep the tablets in the original package!

6. FURTHER INFORMATION

What Metoprolol 50 mg film-coated tablets contain

The active substance is metoprolol tartrate.

Each film-coated tablet contains 50 mg metoprolol tartrate.

The excipients are:

Tablet core: microcrystalline cellulose, lactose monohydrate, povidone, sodium starch glycollate, croscarmellose sodium,colloidal anhydrous silica, magnesium stearate, purified talc.

Film coating: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc.

Content of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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