**PACKAGE LEAFLET: Information for the user**

# METOPROLOL

**Tablets – 100 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:**

- management of arterial hypertension;
- angina pectoris;
- cardiac arrhythmias;
- myocardial infarction;

- adjuvant treatment in hyperthyroidism;
- migraine prophylaxis.

## 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.

Metoprolol is contraindicated in patients with: marked sinusal bradycardia, second or third degree AV block, cardiogenic shock, congestive heart failure, peripheral vascular diseases, phaeochromocytoma, sick sinus syndrome, Prinzmetal's angina, hypotension, severe asthma or bronchospasma, metabolic acidosis.

The drug is contraindicated in the treatment of acute myocardial infarction associated with hypotension (systolic pressure < 100 mm Hg).

### Take special care with Metoprolol

Ask your doctor before taking Metoprolol.

Metoprolol should be used with caution in patients:

- with inadequate myocardial function, since congestive heart failure may be precipitated by β-adrenergic blockade;
- with sinus node dysfunction, since the drug can depress it automatically;
- with heart conduction disorders (first degree AV block);
- with a history of asthma, bronchospasma or obstructive respiratory diseases; cardioselective beta-blockers as Metoprolol can be taken with extreme caution when there is no alternative treatment;
- who suffer from hyperthyroidism or thyrotoxicosis, because Metoprolol may mask the symptoms;
- who suffer from diabetes because Metoprolol may mask the symptoms of hypoglycemia;
- who suffer from psoriasis or myasthenia gravis;
- who suffer from renal or hepatic diseases;
- who are elderly;
- who are allergic because Metoprolol can increase sensitivity to allergens causing a more severe hypersensitivity reaction and may reduce the response to adrenaline;

- who are about to undergo surgery requiring anaesthetic use; it is of the greatest importance that the anaesthetist is aware that Metoprolol is being taken;
- who manifest eye disorders because during treatment with Metoprolol tear production may be reduced.

Abrupt withdrawal of metoprolol should be avoided in patients with cardiac diseases, since it may cause a deterioration of angina symptoms, myocardial ischemia, myocardial infarction.

**Taking other medicines**

Concomitant treatment with other drugs may affect or be affected by Metoprolol.

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

Remember to tell your doctor about the treatment with Metoprolol, if you are perscribed another drug during treatment.

It is especially important that your doctor be aware if you are already being treated with:

- antiacids: the biodisponibility of metoprolol is increased from the concomitant treatment with antiacids which contain aluminium or magnesium salts;
- antiarrhythmics: the combination of beta-blockers with antiarrhythmics may cause myocardial depression; the risk of bradycardia is also increased in combination with flecainide, as well as bradycardia and AV block with amiodarone;
- other antihypertensives, alpha-blockers, anesthetics, MAO-inhibitors, phenothiazines, anxiolytics and hypnotics: may enhance the hypotensive effect;
- calcium-channel blockers: the combination of beta-blockers with calcium-channel blockers results in hypotension; severe hypotension and heart failure with nifedipine; increased risk of AV block and bradycardia with diltiazem; asystole, severe hypotension and heart failure with verapamil;
- adrenaline and other similar substances with sympathomimetic activity;
- clonidine: increased risk of withdrawal hypertension caused by abrupt withdrawal of clonidine in patients who are taking beta-blockers (withdraw beta-blockers several days before slowly withdrawing clonidine);
- nonsteroidal antiinflammators, corticosteroids and oestrogens: may reduce the antihypertensive effect of metoprolol;

- opioid analgesics: the biodisponibility of metoprolol increases by the concomitant treatment with opioid analgesics;
- cardiac glycosides: the risk of AV block and bradycardia is increased if they are administered simultaneously with metoprolol;
- other beta-blockers (including those used in the form of eye drops);
- cimetidine: plasma concentration of metoprolol is increased when taken concomitantly with cimetidine;
- rifampicin: plasma concentration of metoprolol is decreased when taken concomitantly with rifampicin;
- paroxetine, because it may increase the plasma concentration of metoprolol;
- antimalarials such as: hydroxychloroquine, quinidine, artemether with lumefantrine; the last combination should not be taken concomitantly with metoprolol;
- some antiviral drugs such as ritonavir, tipranavir and antifungals such as terbinafine;
- moxisylyte: may cause severe postural hypotension if taken concomitantly with beta-blockers;
- fingolimod: may increase the risk of bradycardia when co-administered with beta-blockers;
- insulin or other drugs used to treat diabetes;
- drugs to treat migraine such as ergotamine.

This list of interactions is not complete. There are other drugs that may interact with metoprolol.

**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**

**Ask your doctor or pharmacist for advice before taking this drug.**

Metoprolol should not be taken during pregnancy, except the case when the doctor considers it necessary and according to the benefit / risk ratio. For this reason, always consult with your doctor before taking Metoprolol during pregnancy.

**Breastfeeding**

Metoprolol passes into the breast milk and for this reason it should not be taken during breastfeeding. However, if the use of Metoprolol is very necessary, the baby should be monitored for the effects that this drug may cause.

**Driving and using machines**

The drug affects the ability to drive or use machines. It may cause tiredness and dizziness.

**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.

## 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. The tablets should be swallowed at least with a half glass of water.

Adults:

- Management of hypertension: 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.
- Angina pectoris: 50 - 100 mg two or three times daily.
- Cardiac arrhythmia: 50 mg two or three times daily, which may be increased if necessary up to 300 mg daily in divided doses.
- As an adjunct in the management of acute myocardial infarction: 5 mg metoprolol tartrate IV at 2-minutes intervals to a total of 15 mg. This should be followed by oral treatment of 50 mg every 6 hours for 2 days.
- As an adjunct in the treatment of hyperthyroidism: 50 mg 4 times daily.
- For migraine prophylaxis: 100 - 200 mg daily in divided doses.

**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.

The symptoms that usually appear after taking a large amount of metoprolol are: bradycardia, hypotension, bronchospasma, acute heart failure, shock, cardiac arrest. Other symptoms are: nausea, vomiting, cyanosis.

The measures that should be taken are gastric lavage and other treatments taken by the doctor in different cases.

**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!

It may be discontinued slowly under medical control. Abrupt withdrawal of beta-blockers may exacerbate the symptoms.

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. Sometimes they are serious, sometimes not. Do not panic by this list of possible side effects. You may not get any of them.

Most of the side effects that appear in patients treated with Metoprolol are as a result of exaggerated therapeutic effects.

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).

Other side effects include:

**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)**

Depression, sleep disorders such as sleepiness, difficulty in sleeping or nightmares, feeling less alert, numbness or tingling in your hands and feet, muscle cramps, heart problems which can cause shortness of breath or ankle swelling (heart failure), irregular heart beat or palpitations, heart conduction disorders, poor blood circulation which makes the toes and fingers numb and pale (Raynaud's phenomenon), bronchospasma, diarrhoea or constipation, skin rash and/or itching.

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

Reduction in blood platelets which increases the risk of bleeding or bruising, weight gain, hallucinations or personality disorders, dry or sore eyes or problems with vision, ringing in the ears (tinnitus), partial loss of hearing or deafness, gangrene in persons with poor peripheral circulation, retroperitoneal fibrosis, runny nose (rhinitis), dry mouth, changes in the results of liver function tests, hepatitis, increased sensitivity to sunlight, worsening of psoriasis, increased sweating, loss of hair (alopecia), impotence or loss of libido, Peyronie’s syndrome (bending of penis), painful joints, chest pain, memory loss.

**Other effects**

Confusion, abnormal levels of certain types of fats in the blood such as decrease of HDL - cholesterol or increase of triglycerides, worsening of intermittent claudication (a cramp - like pain brought on by exercise).

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 in the original package!

## 6. FURTHER INFORMATION

**What Metoprolol 100 mg tablets contain**

**The active substance** is Metoprolol tartrate.

Each tablet contains 100 mg metoprolol tartrate.

**The excipients** are lactose monohydrate, microcrystalline cellulose, magnesium stearate, povidone, sodium starch glycolate, colloidal anhydrous silica, sodium croscarmellose, purified talc.

**Content of the pack**

Box with 30 tablets.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

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**This leaflet was last revised in September 2023.**