

PACKAGE LEAFLET: INFORMATION FOR THE USER

Metoprolol Tartrate 50 mg tablets Metoprolol Tartrate 100 mg tablets 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

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1. What Metoprolol Tartrate tablets are and what they are used for
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1. What Metoprolol Tartrate tablets are and what they are used for

The active ingredient, metoprolol tartrate, belongs to a group of drugs called beta blockers.

Metoprolol tartrate has an effect on how the heart works and reduces blood pressure. Metoprolol tartrate can be used to treat a number of conditions. It can be prescribed to patients:

- to reduce high blood pressure
- with chest pain due to angina
- with fast or irregular heart rhythm
- who have had a heart attack, as protection against a possible further heart attack
- to prevent migraines

Metoprolol is for use in adults.

2. Before you take Metoprolol Tartrate tablets

Do not take Metoprolol Tartrate tablets

- if you are allergic (hypersensitive) to metoprolol or any of the other ingredients in this medicine (see section 6: Further information)
- if you are allergic to a group of drugs called beta blockers.
- if you have a condition affecting the conduction of electrical impulses in the heart (second and third degree heart block)
- if you have severe heart failure
- if you are suffering from shock, due to your heart not pumping properly
- if you have seriously poor circulation
- if you have a very slow heart rate (less than 50 beats per minute)
- if you are receiving group of drugs called beta-agonists which are used to help the heart pump more strongly
- if you are suffering from heart rhythm problems known as sick sinus syndrome
- if you have or have had breathing difficulties or asthma
- if you are suffering from untreated high blood pressure due to a tumour near the kidney (phaeochromocytoma)
- if you are suffering from increased acidity of the blood (metabolic acidosis)
- if you are receiving verapamil or diltiazem by intravenous injection,
- If you have very low blood pressure

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow his advice.

Take special care with Metoprolol Tartrate tablets

It is important to tell your doctor before taking Metoprolol Tartrate tablets

- if you want to discontinue treatment: you should not stop suddenly, as this can aggravate chronic heart failure and increase the risk of a heart attack.
- If you have breathing problems.

- If you get allergic reactions, for example to insect stings, foods or other substances,
- if you have diabetes. Metoprolol can mask some symptoms of low blood sugar in diabetics. It may also be necessary to adjust any treatment with blood sugar reducing agents that you already receive..
- If you have poor blood circulation or heart failure.
- If you have a slow heartbeat.
- If you have to undergo an operation, please tell your anaesthetist that you are taking Metoprolol Tartrate tablets.
- If you have severe liver problems.
- If you have a tumour near the kidney (phaeochromocytoma)
- If you have a type of chest pain called Prinzmetal's angina.
- If you have an overactive thyroid (symptoms such as increased heart rate, sweating, tremor, anxiety, increased appetite or weight loss may be hidden by this medicine)
- If you have or have suffered from skin rashes called psoriasis
- If you suffer from dry eyes

Consult your doctor if one of the above warnings applies to you, or has done so in the past.

Taking other medicines

Metoprolol Tartrate tablets can affect how some other medicines work, and some medicines can also affect how metoprolol work.

If Metoprolol Tartrate tablets are to be combined with the medicines listed below, you must consult your doctor:

- Medicines used to lower blood pressure including
 - Calcium antagonists e.g verapamil, nifedipine and diltiazem
 - Centrally acting agents e.g clonidine, guanfacin, moxonidine, methyldopa, and rilmenidine
 - Alpha blockers e.g prazosin, tamsulosin, terazosin, doxazosin

The effects of metoprolol and other blood pressure lowering drugs on blood pressure are usually additive.

- Rifampicin (used in tuberculosis)
- Medicine used to treat allergies (antihistamines)
- Medicines used to treat depression (antidepressants)
- Medicines used to treat serious mental illness (antipsychotics)
- Medicines used to reduce inflammation and fever for example celecoxib, indomethacin and floctafenine.
- Other beta blocker medicines similar to metoprolol including those in the form of eye drops such as timolol.
- Ergotamine (used in migraine)
- Nitrates such as nitroglycerine (used in angina)
- Narcotics such as oxycodone (used to control severe pain)
- Digitalis glycosides such as digoxin (used in heart failure).
- Medicines used to treat abnormal heart rhythm such as propafenone, amiodarone and quinidine.
- Atropine (used for treating certain eye conditions)
- Adrenaline (used for emergency treatment of allergic reactions).
- Anaesthetics.
- Medicines used to treat diabetes
- Lidocaine (used to treat abnormal heart rhythm).
- Baclofen (used to treat spastic conditions).
- Mefloquine (used in malaria).
- Antacids (used for stomach upsets)

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

Taking Metoprolol Tartrate tablets with food and drink

You should minimise your alcohol intake when taking this medicine as it may increase the effect of metoprolol.

Pregnancy and breast-feeding

Pregnancy

Metoprolol Tartrate is not generally recommended during pregnancy although your doctor may decide to use metoprolol in late pregnancy under close supervision including any effects on the newborn infant.

Please inform your doctor if you are pregnant.

Breast-feeding

Breast-feeding should be generally discontinued during treatment with metoprolol although your doctor may decide to use metoprolol in a nursing mother with close supervision of the infant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Metoprolol may influence your ability to drive and use machines because it may cause dizziness and fatigue. This applies to a greater extent at the beginning of treatment. Do not drive or use any tools or machines if side effects such as fatigue or dizziness occur.

3. How to take Metoprolol Tartrate tablets

Always take Metoprolol Tartrate tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed on an empty stomach.

The usual dose is:

- in the case of high blood pressure (hypertension): 100 or 200 mg, preferably once a day, as a single dose in the morning, or in divided doses (morning and evening). Your doctor may ask you to start with a lower dose.
- in the case of chest pain (angina): depending on the symptoms 100 to 200 mg per day, in divided doses (morning and evening). Your doctor may ask you to start with a lower dose.
- in the case of abnormal heart rhythm: 100 to 150 mg per day, in divided doses (in the morning and in the evening). If necessary, your doctor can increase your dosage further.
- as protection against a further heart attack: 100 mg twice a day (in the morning and in the evening).
- to prevent migraines: 100 to 200 mg per day, in divided doses, in the morning and evening.

This medicine is generally taken for long-term. Never change the dosage yourself.

The dose may be reduced in patients with severe liver problems.

The tablet can be divided into equal doses.

Use in children: Metoprolol Tartrate tablets are not recommended for children.

If you take more Metoprolol Tartrate tablets than you should

Symptoms of overdose include a low blood pressure, slow heart beat, shortness of breath, dizziness, fatigue, cough, wheezing and, in severe cases, cardiac arrest. Contact your doctor immediately. Take with you the empty packs of the medicines you consumed. Sometimes, hospitalisation may be necessary.

If you forget to take Metoprolol Tartrate tablets

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Metoprolol Tartrate tablets

Never suddenly stop taking Metoprolol Tartrate tablets. If you suddenly stop taking the medicine, then your physical condition may deteriorate immediately, abnormalities in your heart rhythm may develop or you may develop high blood pressure.

Discontinuing metoprolol treatment should always be undertaken in consultation with your doctor who will direct you how to gradually reduce the dose until the treatment is stopped altogether.

If you suffer problems during the tapering-off period, consult your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Metoprolol Tartrate tablets can cause side effects, although not everybody gets them.

Stop treatment and contact a doctor at once if you have the following symptoms of:

- an allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- very slow heart and blood pressure (you may feel very dizzy or weak) or in case of breathing difficulties.

The following terms are used to describe how often side effects have been reported.

Very common: affects 1 or more than 1 user in 10

Common: affects 1 to 10 users in 100

Uncommon: affects 1 to 10 users in 1,000

Rare: affects 1 to 10 users in 10,000

Very rare: affects less than 1 user in 10,000

Very common:

- fatigue

Common:

- dizziness
- headache
- slow heart rate
- low blood pressure which might make you faint or dizzy particularly when standing up quickly from a sitting or lying position
- irregular heart beat
- poor blood circulation which makes the toes and fingers numb and pale
- Shortness of breath on exertion
- feeling sick
- abdominal pain
- diarrhoea
- constipation

Uncommon:

- an increase in weight
- depression
- reduced alertness
- drowsiness
- difficulty in sleeping
- nightmares
- abnormal skin sensations (tingling, tickling, itching or burning)
- muscle weakness and cramps
- an aggravation of heart failure
- water retention
- chest pain
- wheezing
- vomiting
- skin rash
- increased sweating

Rare:

- nervousness
- anxiety
- difficulty or loss of interest in sex
- eye problems (blurred vision, dry and/or irritated eyes, inflammation)
- runny nose
- dry mouth
- abnormal blood test results of liver function
- reversible hair loss

Very rare:

- severe reduction in number of white blood cells which makes infections more likely
- reduction in blood platelets, which increases risk of bleeding or bruising
- change in levels of blood fats.
- low blood sugar in diabetics taking insulin
- memory impairment
- confusion
- hallucination
- personality changes
- ringing in the ears

- reversible hearing loss
- gangrene
- taste disorders
- inflammation of liver (hepatitis)
- hypersensitivity to light
- deterioration in psoriasis
- joint pain
- abnormal curvature of the penis

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.

5. How to store Metoprolol Tartrate tablets

- Keep out of the reach and sight of children.
- Do not use Metoprolol Tartrate tablets after the expiry date, which is stated on the blister and the carton after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Metoprolol Tartrate tablets contains

The active substance is Metoprolol tartrate.

Each tablet contains 50/100 mg Metoprolol tartrate.

The other ingredients are:

Cellulose microcrystalline (E460), Gelatin (E441), Sodium starch glycolate, Silica colloidal hydrated (E551), Stearic acid

What Metoprolol Tartrate tablets looks like and contents of the pack

50 mg tablets: White to off-white, approximately 8 mm round, biconvex tablet marked  on one side and a scoreline on the other side.

100 mg tablets: White to off-white, approximately 10 mm round, biconvex tablet marked  on one side and a scoreline on the other side.

Metoprolol Tartrate tablets are available in PVC/PVdC-Aluminium blister packs containing 10, 20, 28, 30, 50, 56, 60, 84 and 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation holder

Accord Healthcare Limited, Sage House, 319, Pinner Road, North Harrow, Middlesex HA1 4HF, United Kingdom

Manufacturer

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