

Package leaflet: Information for the patient

Metoprolol tartrate 50 mg film-coated tablets Metoprolol tartrate 100 mg film-coated tablets metoprolol tartrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Metoprolol Tartrate tablets
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1. What Metoprolol Tartrate tablets are and what they are used for

Metoprolol tartrate belongs to a group of medicines called beta blockers.

It is used to treat:

- high blood pressure
- angina pectoris (pain in the chest caused by blockages in the arteries to the heart)
- irregular heart rhythm (arrhythmia)
- the symptoms caused by an overactive thyroid gland (thyrotoxicosis)

It is used to **prevent**:

- heart damage and death due to heart attacks
- migraine

2. What you need to know before you take Metoprolol Tartrate tablets

Do not take Metoprolol Tartrate tablets if you:

- are allergic to metoprolol, other beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- suffer with **heart conduction** or **rhythm problems**
- have severe or uncontrolled heart failure
- are in shock caused by heart problems
- suffer with **blocked blood vessels**, including **blood circulation problems** (which may cause your fingers and toes to tingle or turn pale or blue)

- have a slow heart rate or have suffered a heart attack which has been complicated by a significantly slow heart rate
- suffer from a tight, painful feeling in the chest in periods of rest (**Prinzmetal's angina**)
- have or have had breathing difficulties or asthma including **COPD** (Chronic Obstructive Pulmonary Disease causing cough, wheezing or breathlessness, phlegm or increase in chest infections)
- suffer with untreated phaeochromocytoma(high blood pressure due to a tumour near the kidney)
- suffer from increased acidity of the blood (metabolic acidosis)
- have low blood pressure
- suffer with **diabetes** associated with frequent episodes of **low blood sugar** (hypoglycaemia)
- have **liver** or **kidney disease** or **failure**
- are given other medicines for blood pressure by injection especially verapamil, diltiazem or disopyramide.

Warnings and precautions

Talk to your doctor or pharmacist before using Metoprolol Tartrate tablets if you:

- have a **history of** allergic reactions, for example to insect stings, foods or other substances,
- have **diabetes mellitus** (low blood sugar levels may be hidden by this medicine)
- have controlled **heart failure**.
- have a **slow heart rate** or **blood vessel disorder**.
- suffer from treated **phaeochromocytoma** (high blood pressure due to tumour near the kidney)
- have or have suffered from **psoriasis** (severe skin rashes)
- have **liver cirrhosis**
- are **elderly**
- have **myasthenia gravis**
- If you suffer from dry eyes.

Anaesthetics and surgery

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking Metoprolol Tartrate tablets, as your heart beat might slow down too much.

Taking other medicines

Do not take Metoprolol Tartrate tablets if you are already taking:

- **monoamine oxidase inhibitors** (MAOIs) for depression
- other **blood pressure lowering** medicines such as verapamil, nifedipine and diltiazem
- **disopyramide or quinidine** (to treat irregular heartbeat (arrhythmia))

Children

Do not give this medicine to children.

Other medicines and Metoprolol Tartrate tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- medicines used to treat stomach ulcers such as **cimetidine**
- medicines used to treat high blood pressure such as **hydralazine, clonidine or prazosin**
- medicines used to treat irregular heart rhythm such as **amiodarone** and **propafenone**
- medicines used to treat depression such as tricyclic or **SSRI antidepressants**
- medicines used to treat epilepsy such as **barbiturates**
- medicines used to treat mental illness such as **phenothiazines**
- **anaesthetics** such as cyclopropane or trichloroethylene
- medicines used to treat some cancers, particularly cancer of the kidney such as **aldesleukin**
- medicines used to treat erectile dysfunction such as **alprostadil**

- **anxiolytics** or **hypnotics** (e.g. temazepam, nitrazepam, diazepam)
- **indometacin** or **celecoxib** (Non-Steroidal Anti-Inflammatory Drugs (NSAIDs))
- **rifampicin** (antibiotic) or terbinafine (antifungal)
- **oestrogens** such as a contraceptive pill or hormone replacement therapy
- **corticosteroids** (e.g. hydrocortisone, prednisolone)
- other **beta-blockers** e.g. eye drops.
- **adrenaline** (epinephrine) or **noradrenaline** (norepinephrine), used in anaphylactic shock or other **sympathomimetics**
- medicines used to treat **diabetes**
- Metoprolol tartrate tablets could increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- **lidocaine** (a local anaesthetic)
- **moxisylyte** (used in Raynaud's syndrome)
- medicines used to treat malaria such as **mefloquine**
- medicines used to prevent nausea and vomiting such as **tropisetron**
- medicines used to treat asthma such as **xanthines** such as aminophylline or theophylline
- medicines to treat **migraines** such as ergotamine
- medicines used to treat heart conditions such as **cardiac glycosides** e.g. digoxin
- medicines used to treat rheumatoid arthritis such as **hydroxychloroquine**
- **diphenhydramine** (sedative antihistamine).

Metoprolol Tartrate tablets and alcohol

You are advised to avoid alcohol whilst taking this medicine. Alcohol may increase the blood pressure lowering effect of metoprolol tartrate.

Pregnancy and breast-feeding

Metoprolol Tartrate tablets are not recommended during pregnancy or breastfeeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Metoprolol Tartrate tablets may make you feel tired and dizzy. If affected, patients should not drive or operate machinery.

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.

Recommended dose:

Recommended dose should not exceed 400 mg/day in any of below mentioned conditions.

- **High blood pressure:** Initially 100 mg metoprolol tartrate daily. The dose may be increased to 200mg daily in single or divided doses.
- **Angina:** 50 to 100 mg metoprolol tartrate two or three times daily.
- **Irregular heart beats:** 50mg metoprolol tartrate two or three times daily. The dose may be increased to 300mg daily in divided doses.
- **Heart attack:** 50mg metoprolol tartrate every six hours. The usual maintenance dose is 200mg daily in divided doses. The medicine should be taken for at least 3 months.
- **Prevention of migraine:** 100 to 200 mg metoprolol tartrate daily in divided doses (in the morning and evening).

- **Overactive thyroid gland (thyrotoxicosis):** 50mg metoprolol tartrate four times daily.
- **Children:** Not recommended.
- **Patients with impaired kidney or liver function:** In such cases the dose should be adjusted. Always follow your doctor's advice.

Swallow the tablet whole. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Metoprolol Tartrate tablets than you should

If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once.

Symptoms of overdose are low blood pressure (fatigue and dizziness), slow pulse, heart conduction problems, shortness of breath, unconsciousness, coma, , cardiac arrest, feeling and being sick ,blue colouring of the skin, low blood sugar levels and high levels of potassium in the blood.

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. Then go on as before. Do not take a double dose to make up for a forgotten dose

If you stop taking Metoprolol Tartrate tablets

Do not suddenly stop taking Metoprolol Tartrate tablets as this may cause worsening of heart failure and increase the risk of heart attack. Only change the dose or stop the treatment in consultation with your doctor.

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

4. Possible side effects

Like all medicines, this medicine 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, tongue or throat, or difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common (may affect up to 1 in 10 people):

- tiredness
- dizziness.
- headache
- a slow heart rate, feeling faint on standing due to low blood pressure
- shortness of breath with or without strenuous physical activity
- feeling or being sick
- stomach pain

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

- depression
- nightmares
- nervousness
- anxiety
- sexual dysfunction or reduced sex drive

- inability to think clearly
- sleepiness or difficulty in sleeping
- tingling or 'pins and needles'
- difficulty breathing
- heart failure
- irregular heart rate
- palpitation
- water retention causing swelling
- Raynaud's phenomenon (causing pain, numbness, coldness and blueness of the fingers)
- diarrhoea or constipation
- skin rash
- muscle cramps

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

- changes in the results of blood tests
- effects on blood clotting causing easy or unexplained bruising
- changes in personality
- confusion
- hallucinations
- visual disturbances
- dry or irritated eyes
- ringing in the ears
- loss of hearing with high doses
- heart conduction problems
- chest pain
- gangrene in patients with severe poor circulation
- runny nose
- dry mouth
- weight gain sensitivity to light
- increased sweating
- hair loss
- worsening or new psoriasis
- joint inflammation (arthritis)
- disturbances of sexual desire and performance
- changes in liver function tests
- taste disorders

Not known (frequency cannot be estimated from the available data):

- worsening or development of limping
- hepatitis (symptoms include fever, sickness and yellowing of the skin or whites of the eyes)
- Peyronie's syndrome (bending of the penis)
- symptoms of high levels of the thyroid hormone or low blood sugar may be hidden
- increase in blood fats or decrease in cholesterol
- retroperitoneal fibrosis (symptoms include lower back pain, high blood pressure)
- occurrence of antinuclear antibodies not associated with systemic lupus erythematosus (SLE).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Metoprolol Tartrate tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, carton and bottle label after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metoprolol Tartrate tablets contains

- The active substance is metoprolol tartrate. Each film-coated tablet contains 50 mg or 100 mg of metoprolol tartrate.
- The other ingredients are:
 - 50mg tablet
Tablet core: lactose monohydrate, cellulose microcrystalline, sodium starch glycolate type A, silica, colloidal anhydrous, croscarmellose sodium, starch, pregelatinised, magnesium stearate.
Tablet coating: hypromellose 15cps, titanium dioxide, talc, macrogol 400, ferric oxide red.
 - 100 mg tablet
Tablet core: lactose monohydrate, cellulose, microcrystalline, sodium starch glycolate type A, silica, colloidal anhydrous, croscarmellose sodium, starch, pregelatinised, magnesium stearate.
Tablet coating: hypromellose 15 cps, titanium dioxide, talc, macrogol 400.

What Metoprolol Tartrate tablets looks like and contents of the pack

Metoprolol tartrate 50 mg film-coated tablets: Pink, round shape having diameter approximately 8mm, biconvex film-coated tablets with scoreline on one side & '50' debossed on other side.

Metoprolol tartrate 100 mg film-coated tablets: White to off-white, round shape having diameter approximately 10 mm, biconvex film-coated tablets with scoreline on one side & '100' debossed on other side.

Metoprolol tartrate film coated tablets 50mg and 100mg are packaged in clear colourless PVC/aluminium blister strips of 10 and 14 tablets.

Pack size: 10, 14, 28, 30, 50, 56, 84 and 100 Tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Batch release site

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