

FLAT DIMENSION = 160 x 480mm
FOLDED DIMENSION = 160 x 30mm

30 mm

Package Leaflet: Information For The User

Metoprolol Tartrate 50mg and 100mg Film-Coated Tablets (metoprolol)

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. 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. See section 4.

What is in this leaflet

1. What Metoprolol tartrate tablets are and what they are used for
2. What you need to know before you take Metoprolol tartrate tablets
3. How to take Metoprolol tartrate tablets
4. Possible side effects
5. How to store Metoprolol tartrate tablets
6. Contents of the pack and other information

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

Metoprolol tartrate, the active ingredient in Metoprolol tartrate tablets, is one of 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**:

- migraine
- heart damage and death due to heart attacks.

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

Do not take Metoprolol tartrate tablets and tell your doctor if you:

- are allergic to metoprolol or to any of the other ingredients of Metoprolol tartrate tablets (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)
- 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
- 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 diabetes associated with frequent episodes of low blood sugar (hypoglycaemia)
- have liver or kidney disease or failure
- have difficulties in passing urine
- have low levels of potassium (hypokalaemia) or sodium (hyponatraemia) in your blood
- have high levels of calcium (hypercalcaemia)
- suffer with gout due to high levels of uric acid (hyperuricaemia) in your blood causing crystals to deposit in joints of hands or feet causing pain
- are given other medicines for blood pressure by injection especially verapamil, diltiazem or disopyramide.

Warnings and Precautions

Take special care and talk to your doctor or pharmacist 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)
- suffer from treated phaeochromocytoma (high blood pressure due to tumour near the kidney)
- have or have suffered from psoriasis (severe skin rashes)
- have a slow heart rate or blood vessel disorder
- have controlled heart failure
- have impaired liver or kidney function
- have liver cirrhosis
- are elderly
- have myasthenia gravis.
- 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 heartbeat 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))

Other medicines and Metoprolol Tartrate tablets

Tell your doctor or pharmacist if you are taking, have taken

recently or might take any other medicines.

- cimetidine (to treat stomach ulcers)
- hydralazine, clonidine or prazosin (to treat high blood pressure)
- amiodarone and propafenone (for irregular heart rhythm)
- tricyclic or SSRI antidepressants (to treat depression)
- barbiturates (to treat epilepsy)
- phenothiazines (for mental illness)
- anaesthetics such as cyclopropane or trichloroethylene
- aldesleukin (to treat some cancers, particularly cancer of the kidney)
- alprostadil (to treat erectile dysfunction)
- anxiolytics or hypnotics (e.g. temazepam, nitrazepam, diazepam)
- indometacin or celecoxib (Non-Steroidal Anti-Inflammatory Drugs (NSAIDs))
- rifampicin (antibiotic) or terbinafine (antifungal)
- cocaine
- 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
- lidocaine (a local anaesthetic)
- moxisylyte (used in Raynaud's syndrome)
- mefloquine (to treat malaria)
- tropisetron (to prevent nausea and vomiting)
- xanthines such as aminophylline or theophylline (to treat asthma)
- medicines to treat migraines such as ergotamine
- cardiac glycosides e.g. digoxin (to treat heart conditions)
- hydroxychloroquine (to treat rheumatoid arthritis)
- diphenhydramine (sedative antihistamine).

Metoprolol 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).

Metoprolol tartrate tablets with alcohol

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

Pregnancy, breast-feeding

Metoprolol Tartrate tablets are not recommended during pregnancy or breastfeeding. If you are pregnant or breastfeeding, 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. Make sure you are not affected before you drive or operate machinery, particularly after changing to another medicine or if taken with alcohol.

Metoprolol tartrate tablets contain Lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Metoprolol tartrate tablets

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

The recommended dose is:

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

- **High blood pressure** - The usual starting dose is 100mg a day. The dose may be increased to 200mg daily in single or divided doses.
- **Angina (Chest pain)** - The usual dose is 50-100 mg taken two or three times a day.
- **Irregular heart beats (arrhythmia)** - 50mg metoprolol tartrate two or three times daily. The dose may be increased to 300mg daily in divided doses.
- **Heart attacks** - 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.
- **Overactive thyroid gland (thyrotoxicosis)** - 50mg metoprolol tartrate four times daily.
- **Prevention of migraine** - 100-200mg metoprolol tartrate daily in divided doses (in the morning and evening).

Children

Metoprolol tartrate tablets is not recommended for children.

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 forget to take Metoprolol tartrate tablets

If you forget to take a dose, take it when you remember and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you take too many Metoprolol tartrate tablets than you should

If you accidentally take too many Metoprolol tartrate tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken. Symptoms of overdose are low blood pressure (fatigue and dizziness), slow pulse, heart conduction problems, heart failure, shock caused by heart problems, cardiac arrest, shortness of breath, unconsciousness, coma, feeling and being sick,

480 mm

blue colouring of the skin, low blood sugar levels and high levels of potassium in the blood.

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:

- an allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue

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)

- Headache, dizziness, or unusual tiredness.
- Slow heartbeat.
- Low blood pressure which might make you faint or dizzy.
- Feeling short of breath when exercising.
- Feeling or being sick, stomachache.

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

- Depression
- Nightmares
- Nervousness
- Inability to think clearly
- anxiety
- sexual dysfunction or reduced sex drive
- palpitation
- Sleepiness or difficulty in sleeping
- Abnormal skin sensations (tingling or 'pins and needles' tickling, itching or burning)
- Breathlessness
- Heart failure
- Irregular heartbeat
- Raynaud's phenomenon (causing pain, numbness, coldness and blueness of the fingers)
- Water retention (oedema)
- Diarrhoea or constipation
- Skin rash
- Muscle weakness and cramps

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

- Hallucinations or personality disorders.
- changes in the results of blood tests
- effects on blood clotting causing easy or unexplained bruising
- weight gain
- Tinnitus or hearing problems.
- Eye problems (blurred vision, dry and/or irritated eyes, inflammation)
- ringing in the ears
- Heart conduction problems
- Chest pain
- Runny nose, dry mouth
- Increased sweating
- Hair loss
- Change in liver function tests
- Gangrene in patients with severe poor circulation.
- Bruising or increased sensitivity of the skin to sunlight, worsening of psoriasis.
- Painful joints (arthritis).
- Severe reduction in number of white blood cells which makes infections more likely
- Reduction in blood platelets, which increases risk of bleeding or bruising
- Abnormal levels of certain types of fats such as cholesterol or triglycerides in the blood.
- Confusion
- disturbances of sexual desire and performance
- 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 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. You can also report side effects directly via the Yellow Card Scheme Website 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

- Do not store above 25°C. Store in the original package.
- Keep out of the sight and reach of children.
- Do not take Metoprolol tartrate tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metoprolol tartrate tablets contain

Each tablet contains 50mg or 100mg of Metoprolol tartrate Ph. Eur as the active ingredient.

The other ingredients are Lactose Monohydrate, Cellulose Microcrystalline, Sodium Starch Glycolate, Silica Colloidal Anhydrous, Croscarmellose Sodium, Starch Pregelatinised, Magnesium Stearate, Hypromellose, Talc, Macrogol, Titanium Dioxide (E171).

Metoprolol tartrate 50mg tablets also contain Ferric Oxide red (E172).

What Metoprolol tartrate tablets look like and contents of the pack

Metoprolol tartrate 100mg tablets are white to off-white, round, biconvex film-coated tablets with 'B' & 'L' separated by notch break line on one side and '100' debossed on other side.

Metoprolol tartrate 50mg tablets are pink, round, biconvex film-coated tablets with 'B' & 'L' separated by notch break line on one side and '50' debossed on other side.

Both the 50mg and 100mg tablets are available in blister packs containing 28 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Metoprolol Tartrate 100mg Film-coated Tablets; PL 17907/0130

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