Package leaflet: Information for the patient

Metoprolol Tartrate 50 mg tablets
Metoprolol Tartrate 100 mg 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:

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

1. What Metoprolol is and what it is used for

Metoprolol belongs to a family of medicines known as beta-blockers. Metoprolol is used:
- to treat high blood pressure (hypertension)
- to prevent and control angina
- to treat cardiac arrhythmias (irregular heart beats)
- to prevent migraines
- as part of the treatment of an overactive thyroid gland (hyperthyroidism)
- to prevent another heart attack when you are recovering from a heart attack (myocardial infarction) or during early stages of heart attack (myocardial infarction) to reduce further damage.

2. What you need to know before you take Metoprolol

Do not take Metoprolol:
- if you are allergic to metoprolol tartrate or to any of the other ingredients of this medicine (listed in section 6)
- if you have suffered an allergic reaction to a beta-blocker medicine in the past
- if you suffer from a slow heart beat (bradycardia) or low blood pressure (hypotension)
- if you suffer from untreated heart failure (when your heart does not pump enough blood around the body) or missed heart beats (heart block)
- if you suffer from sick sinus syndrome (a type of irregular heartbeat) unless you have an artificial pacemaker fitted
- if you have severe disturbances to your circulation outside of your heart (e.g. if you suffer from hardened arteries)
- if you have severe asthma or history of severe lung disease e.g. emphysema
- if you have a rare tumour called a phaeochromocytoma that is not being treated
- if you have been fasting for a long period
- if your blood is more acid than normal (metabolic acidosis)

Warnings and precautions
Talk to your doctor or pharmacist before taking metoprolol
- if you have ischaemic heart disease (when the heart does not get enough blood)
- if you have unstable angina (Prinzmetal's angina)
- if you have a history of heart failure
- if you have poor blood circulation (e.g. Raynaud's disease, intermittent claudication)
- if you have or develop a slow heart rate. If this causes unwanted symptoms your doctor may reduce your dose.
- if you have a rare tumour called a phaeochromocytoma. You should only take Metoprolol if your doctor gives you another medicine to take at the same time called an alpha-blocker.
- if you have ever had psoriasis
- if you have a history of allergies or had severe allergic reactions, asthma or wheezing . Metoprolol may also reduce the effectiveness of medicines used to treat severe allergic reactions, such as adrenaline.
- if you have a thyroid problem as the effects of an overactive thyroid gland (thyrotoxicosis) may be hidden by beta-blocker medicines
- if you need to have surgery and will be given an anaesthetic; tell your doctor, dentist or hospital staff. You will have to stop taking Metoprolol at least 24 hours before surgery.
- if you need anti-allergy treatment e.g. following a wasp or bee sting. Your doctor may wish to interrupt your Metoprolol treatment to prevent a possible allergic reaction.
- if you are diabetic. Metoprolol may make your diabetes worse. You should be aware that the symptoms of low blood sugar (hypoglycaemia) may be hidden by beta-blocker medicines.
- if you have serious liver problems

Tell your doctor if any of the above applies to you.

Other medicines and Metoprolol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including the following as they may interact with your medicine:
- medicine to treat mental illness called a MAOI (Monoamine Oxidase Inhibitor) e.g. phenelzine, or thioridazine
- clonidine. If you take clonidine at the same time as Metoprolol you should not stop taking clonidine until several days after you stop taking Metoprolol
- verapamil if you have a problem with the electrical conduction of your heart beat. You should not take either drug intravenously (in a vein) within 48 hours of stopping the other
- medicine to treat an abnormal heart rhythm e.g. disopyramide, quinidine, amiodarone, sotalol, hydroquinidine, ibutilide, dofetilide, propafenone, diltiazem
- other medicine to treat a heart condition, high blood pressure, angina or migraine e.g. nifedipine, reserpine, digoxin, methyldopa, guanfacine, moxonidine , rilmenitidine, prazosin or glyceryl trinitrate
- other beta-blockers including those used in the form of eye-drops
- drugs which affect the peripheral circulation (fingers and toes) such as ergotamine (used to treat migraine)
- diuretics ('water tablets') e.g. chlorthalidone, hydrochlorothiazide
- diabetic medicine e.g. insulin, glibenclamide. Blood sugar levels need to be monitored closely
- 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)
- oral contraceptives
- cough and cold remedies bought over the counter (including nose and eye drops)
- cimetidine (to treat stomach ulcers), rifampicin (an antibiotic), anti-inflammatory medicines e.g. indometacin, lidocaine (used to treat arrhythmias and used an anaesthetic)
- medicine containing adrenaline given by injection . Rarely, this can give you high blood pressure and a slow heartbeat

- antihistamines (to treat allergies) e.g. diphenhydramine, anti-malarials e.g. hydroxychloroquine, anti-fungals e.g. terbinafine, antivirals (to treat viral infections) e.g. ritonavir
- antidepressants e.g. fluoxetine and paroxetine
- bupropion (to help you stop smoking)

Ask your doctor or pharmacist if you are not sure if you are taking any of the above medicines.

Metoprolol with alcohol
Drinking alcohol can increase the effect of this medicine and you may feel dizzy.

Pregnancy and breast-feeding
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. Its effect in pregnancy is not known but some beta-blockers can affect the growth of your unborn baby. Metoprolol can pass into your breast milk. **Do not** breast-feed your baby unless you have spoken to your doctor first.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Do not drive or operate machines if you feel dizzy or tired while taking this medicine.

Metoprolol contains lactose
The tablets contain **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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets whole with a glass of water.

Adults:

High blood pressure: The recommended starting dose is 100 mg of Metoprolol once a day. If needed your doctor may increase the dose in weekly intervals.
Angina: 50 – 100 mg two or three times a day.
Irregular heart beat/palpitations: 50 mg two or three times a day, up to 300 mg a day.
To prevent migraines: 100 – 200 mg divided in doses in the day, morning and evening.
Overactive thyroid gland: 50 mg four times a day.
To prevent a heart attack/severe chest pain: 50 mg every six hours 15 minutes after your last injection of metoprolol for two days, followed by up to 100 mg twice daily.

Patients with liver problems
If you have liver problems, your doctor will give you a lower dose than stated above.

Use in children and adolescents
Do not take Metoprolol if you are a child or adolescent.

Use in older people
Your doctor will work out the best dose for you.

If you take more Metoprolol than you should

Contact your doctor or casualty department immediately. Take the container and any remaining tablets with you.
The symptoms of overdose include heart conditions which have the following symptoms; dizziness, light headedness, slow pulse, white skin, blue skin, sweating, weakness, fainting, shortness of breath, wheezing, ankle swelling, low blood pressure, low blood sugar, severe confusion, feeling or being sick, fits, unconsciousness and coma.

If you forget to take Metoprolol

Do not take a double dose to make up for a forgotten dose. Take the next dose on time. If you miss several doses, contact your doctor.

If you stop taking Metoprolol

Your condition may worsen rapidly. If you need to stop, your doctor will reduce your dose slowly over 10 days.

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.

If any of the following happen, stop taking Metoprolol and tell your doctor immediately or go to the nearest hospital emergency department:

Rare side effects (may affect up to 1 in 1,000 people)
- wheezing or coughing or worsening of asthma
- heart failure which may cause swollen ankles and breathlessness

Very rare side effects (may affect up to 1 in 10,000 people)
- gangrene

Not known (frequency cannot be estimated from the available data)
- retroperitoneal fibrosis where abnormal scar tissue occurs behind the membrane that lines the cavity of the abdomen. This may present with pain in the back, groin or the lower abdomen.
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis)

Other side effects

Common side effects (may affect up to 1 in 10 people)
- headache
- slowing of the heart beat
- feeling or being sick
- stomach pain or discomfort
- feeling tired
- dizziness
- shortness of breath when exercising
- low blood pressure, which may make you feel dizzy or faint on standing up, especially when getting up from a sitting or lying position

Rare side effects (may affect up to 1 in 1,000 people)
- feeling depressed or decreased mental alertness
- sleep problems
- tingling or numbness in the arms and legs
- diarrhoea or constipation
- painful cold fingers and toes or worsening of circulation problems (e.g. Raynaud's disease)
- an irregular heart rhythm or missed beats (palpitations)
- muscle cramps
- nightmares
- allergic skin reactions (rash; itchy, swollen red skin; hives)

Very rare effects (may affect up to1 in 10,000 people)
- disturbed conduction of the heart rhythm
- dry eyes or impaired vision (which can also affect contact lens wearers)
- dry mouth
- abnormal liver function
- itchy runny nose
- ringing in the ears or hearing problems
- sweating or weight gain
- pain and swelling in the joints (arthritis)
- mood changes
- hallucinations
- pain in front of the heart
- hair loss
- blood problems
- sensitivity to sunlight
- worsening of psoriasis
- impotence or loss of sex drive

Not known (frequency cannot be estimated from the available data)
- positive anti-nuclear antibodies (an indicator of autoimmune disease where the body attacks its own tissues)
- abnormal curvature of the penis with painful erections (Peyronie's disease)
- confusion
- abnormal levels of certain types of fats such as cholesterol or triglycerides in the blood
- conjunctivitis

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.

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

5. How to store Metoprolol

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 pack after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C.

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

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 contains
The active substance is metoprolol tartrate. Each tablet contains either 50 mg or 100 mg of metoprolol tartrate.
The other ingredients are lactose monohydrate, microcrystalline cellulose, povidone K29/32, colloidal anhydrous silica, magnesium stearate and sodium starch glycollate.

What Metoprolol looks like and contents of the pack
Metoprolol Tartrate 50 mg tablets: White, biconvex tablets marked “ML” score line “50”one side and “G” on reverse
Metoprolol Tartrate 100 mg tablets: White biconvex tablets marked “ML” score line “100” one side and “G” on reverse.

Metoprolol is available in blister packs or in pots (with an optional filler) in pack sizes of 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180 and 500 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer
Generics [UK] Ltd, Potters Bar, Hertfordshire, EN6 1TL, UK

Gerard Laboratories Ltd, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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