Package leaflet: Information for the user

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

1. What Metoprolol tartrate is and what it is used for

Metoprolol tartrate contains metoprolol tartrate, which belongs to a group of medicines called beta-blockers. Metoprolol tartrate reduces the effect of the stress hormones on the heart in connection with physical and mental exertion. This results in the heart beating slower (pulse rate is reduced).

It is used to **treat**:
- high blood pressure
- angina pectoris (pain in the chest caused by lack of oxygen in the heart)
- irregular heart rhythm (arrhythmia). in adults.

It is used to **prevent**:
- migraine
- heart damage, heart death or further heart attacks after a heart attack. in adults.

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

Do not take Metoprolol tartrate if you:
- are allergic to metoprolol tartrate, other beta-blockers or any of the other ingredients of this medicine (listed in section 6).
- have **heart conduction problems** *(*serious *AV-block or sinoatrial block)*
- suffer from sick sinus syndrome
- have **untreated heart failure,** are receiving treatment to **increase heart contractions** or are in **shock** caused by heart problems
- suffer from severely **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** (less than 50 beats/ min)
- have **low blood pressure**
- suffer from **increased acidity of the blood** (metabolic acidosis)
- have **severe asthma** or **COPD** (chronic obstructive pulmonary disease)
- are receiving other blood pressure lowering medicines such as verapamil and diltiazam by intravenous injection. See also “Other medicines and Metoprolol tartrate”
- are using antiarrrhythmics such as disopyramide. See also “Other medicines and Metoprolol tartrate”
- have untreated high blood pressure due to tumour of the adrenal medulla (phaechromocytoma**)**.

Warnings and precautions
Talk to your doctor or pharmacist before taking Metoprolol tartrate if you:
- have **asthma**
- have **diabetes mellitus** (low blood sugar levels may be hidden by this medicine)
- have high blood pressure due to tumour of the adrenal medulla (treated phaeochromocytoma)
- are having **treatment** to reduce **allergic reactions**. Metoprolol tartrate may increase your hypersensitivity to the substances you are allergic to and increase the severity of allergic reactions
- have an **overactive thyroid,** (symptoms such as increased heart rate, sweating, tremor, anxiety, increased appetite or weight loss may be hidden by this medicine)
- have or have suffered from skin rashes called psoriasis
- suffer from blood circulation problems (in the fingers, toes, arms and legs)
- suffer from a heart conduction disorder (AV block)
- have a type of chest pain called Prinzmetal’s angina.
- have **heart failure and one of the following:**
- had a heart attack or angina attack in the last 28 days
- reduced kidney or liver function
- are under 40 years old or over 80 years old
- diseases of the heart valves
- enlarged heart muscle
- had heart surgery in the last 4 months
- have unstable heart failure .

If are going to have an anaesthetic, please tell your doctor or dentist that you are taking Metoprolol tartrate.

Children and adolescents
There is limited data on the use of metoprolol in children and adolescents, therefore the use of metoprolol is not recommended.

Other medicines and Metoprolol tartrate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Metoprolol tartrate tablets can affect how some other medicines work, and some medicines an also affect how metoprolol work. If Metoprolol tartrate tablets are to be combined with the medicines listed below, you must consult your doctor before taking this medicine:

<u>The following combination with metoprolol should be avoided:</u>
- Barbituric acid derivatives e.g. phenobarbital (used to treat epilepsy)
- Propafenone, quinidine, verapamil, diltiazem, nifedipine and amlodipine (used to treat cardiovascular disease)

<u>The following combinations with metoprolol may require dose adjustment:</u>
- Amiodarone, disopyramide (for irregular heart rhythm)
- Indomethacin, sulindac, diclofenac and foctafenine (medicines used to reduce inflammation, fever and pain)
- Fluoxetine, paroxetine and bupropion (medicines used to treat depression)
- Thioridazine (antipsychotic)
- Ritonavir (antiretroviral)
- Diphenhydramine (antihistamine)
- Hydroxychloroquine, mefloquine (used in malaria)
- Terbinafine (for fungal infection of skin)
- Cimetidine (for ulcers)
- Digitalis glycosides such as digoxin (used in heart failure)
- Epinephrine (medicine used in acute shock and severe allergic reaction)
- Phenylpropanolamine (used to reduce swelling of the nasal mucosa)
- Other beta blockers e.g. eye drops
- Monoamine oxidase inhibitors (MAOIs) (used to treat depression and Parkinson’s disease)
- Clonidine, guanfacin, moxonidine, methyldopa, rilmenidine (blood pressure lowering medicines)
- Ergotamine (used in migraine)
- Nitrates such as nitroglycerine (used in angina)
- General anaesthetics
- Insulin and oral antidiabetic (for reducing blood sugar level) medicines
- Prazosine, tamsulosin, terazosine, doxazosine (alpha blockers, used to treat high blood pressure and benign prostatic hyperplasia)
- Lidocaine (local anaesthetic)
- Rifampicine (used to treat tuberculosis)
- Antacids (used for stomach upsets).

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

Pregnancy, breast-feeding and fertility
Metoprolol tartrate is 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 may make you feel tired and dizzy. Make sure you are not affected before you drive or operate machinery.

<u>Metoprolol contains sodium.</u>
This medicine contains less than 1 mmol sodium (23 mg) per tablets, that is to say essentially ‘sodium-free’.

3. How to take Metoprolol tartrate

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Metoprolol tartrate should be taken without food and on an empty stomach.
Metoprolol tartrate tablets can be divided into equal doses.

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The recommended dose is:
- **High blood pressure:**
  Initially 100 mg daily.
- **Angina pectoris:**
  Usually 50-100 mg twice daily.
- **Irregular heart beats (arrhythmia):**
  100-200 mg daily.
- **Preventive therapy after a heart attack:**
  The usual maintenance dose is 100 mg twice daily.
- **Prevention of migraine:**
  50-100 mg twice daily.

If you take more Metoprolol tartrate 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. Depending on the extent of the overdose, this can lead to excessive reduction in blood pressure and a decrease in heart rate. As a consequence of the failure of heart function, this can even lead to cardiac arrest, heart muscle weakness and shock. Other symptoms include problems in breathing, constriction of the muscles in the respiratory tract, vomiting, disturbances of consciousness and even occasionally generalised seizures.

If you forget to take Metoprolol tartrate
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
Do not suddenly stop taking Metoprolol tartrate 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:
- **an allergic reaction** such as itchy skin rash, flushing, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:
Very common (may affect more than 1 in 10 people):
- feeling faint on standing due to low blood pressure, tiredness.

Common (may affect up to 1 in 10 people):
- slow heart rate,
- difficulties in maintaining balance (very rare with fainting),
- cold hands and feet,
- palpitation,
- dizziness,
- headache,
- feeling sick,
- diarrhoea,
- constipation,
- stomach pain,
- shortness of breath with strenuous physical activity.

Uncommon (may affect up to 1 in 100 people):
- chest pain,
- weight gain,
- depression
- concentration problems
- inability to sleep (insomnia)
- drowsinees
- nightmares
- tingling in the skin,
- temporary worsening of symptoms of heart failure
- disturbances in the conduction of the heart
- spasmodic contraction of the smooth muscle of the bronchi (causing shortness of breath),
- vomiting
- rashes
- increased sweating
- fluid retention
- muscle cramps

Rare (may affect up to 1 in 1,000 people):
- worsening of diabetes,
- nervousness,
- anxiety,
- visual disturbances,
- dry or irritated eyes,
- conjunctivitis,
- impotence, other sexual dysfunctions,
- Peyronie's syndrome (bending of penis on erection),
- irregular heart beat,
- heart conduction disturbances,
- dry mouth,
- runny nose,
- hair loss,
- changes in liver function tests.

Very rare (may affect up to 1 in 10,000 people):
- changes in blood cells,
- forgetfulness, memory impairment
- confusion,
- hallucinations,
- personality changes e.g. mood changes,
- ringing in the ears (tinnitus),
- hearing problems,
- taste changes,
- inflammation of the liver (hepatitis),
- sensitivity to light,
- worsening or new psoriasis, psoriasis like changes
- muscle weakness,
- joint pain,
- tissue death in patients with severe circulation disturbances.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: 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 tartrate

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 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 contains
- The active substance is metoprolol tartrate. Each film-coated tablet contains 50 mg or 100 mg of metoprolol tartrate.
- The other ingredients are:
  Tablet core: Cellulose microcrystalline, maize starch, sodium starch glycolate, silica colloidal anhydrous, sodium laurilsulfate, talc, magnesium stearate.
  Tablet coating:
  50 mg: Hypromellose, titanium dioxide (E171), polysorbate 80, talc, iron oxide red (E172).
  100 mg: Hypromellose, titanium dioxide (E171), macrogol, polysorbate 80, talc, indigo carmine aluminium lake (E132).

What Metoprolol tartrate looks like and contents of the pack
Metoprolol tartrate 50 mg:
Peach coloured, round shaped [diameter 8.1 mm], film-coated tablets, debossed with 'C over 74' on one side and deep score line on the other side. The tablet can be divided into equal doses.

Metoprolol tartrate 100 mg:
Light blue coloured, round shaped [diameter 10.6 mm], film-coated tablets, debossed with 'C over 75' on one side and deep score line on the other side. The tablet can be divided into equal doses.

Metoprolol tablets are available in PVC/PVdC – Aluminium blister pack: 20, 28, 30, 50, 56, 60 and 100 tablets.
HDPE bottle pack with polypropylene closure: 30 and 500 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder
Milpharm Limited
Ares Block, Odyssey Business Park, West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
Ares Block, Odyssey Business Park, West End Road
Ruislip HA4 6QD
United Kingdom

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