PACKAGE LEAFLET: INFORMATION FOR THE USER

Metoprolol Teva 25 mg prolonged-release tablets
Metoprolol Teva 50 mg prolonged-release tablets
Metoprolol Teva 100 mg prolonged-release tablets
Metoprolol Teva 200 mg prolonged-release tablets

Metoprolol succinate

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 Teva is and what it is used for

Metoprolol Teva belongs to a group of medicines known as beta blocking agents. Metoprolol reduces the effect of stress hormones on the heart in connection with physical and mental exertion. This results in the heart beating slower (pulse rate is reduced).

Metoprolol Teva prolonged-release tablets are used:
Adults:
- for the treatment of high blood pressure
- to prevent angina pectoris
- for the treatment of heart failure
- for the treatment of palpitation (unduly rapid or irregular heart beat) in some cases
- for the treatment of certain types of arrhythmia (irregular heart beat)
- for prophylactic treatment after an acute heart attack
- prophylactic treatment for migraine.

Children and adolescents from 6-18 years:
- for treating high blood pressure

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

Do not take Metoprolol Teva
- if you are allergic (hypersensitive) to metoprolol succinate, other similar medicines (beta-blockers) or to any of the other ingredients of this medicine (listed in section 6)
- if you are suffering from shock due to severe heart problems,
- if you suffer from a diseased sinus node in the heart (sick sinus syndrome),
- if you have a serious heart block (conduction disorder)
- if you suffer from untreated heart insufficiency,
- if you have very low blood pressure and/or a very low heart rate,
- if you have recently suffered a heart attack and have the following special conditions (heart rate

less than 45 beats per minute, abnormal ECG, the upper value of your blood pressure is less than 100 mmHg).
- if you suffer from heart insufficiency and your upper value of your blood pressure is less than 100 mmHg at lying,
- if you suffer from advanced blood circulation disorder in the arms or/and legs

Warnings and precautions
Talk to your doctor or pharmacist before taking Metoprolol Teva if you have any one of the following conditions:
- asthma
- considerable problems with narrowing of the bronchi
- severe acute conditions with a high concentration of acid agents in the body (acidosis)
- vasospastic angina due to spasms of the coronary arteries (Prinzmetal's angina)
- severe kidney impairment
- intermittent claudication; the condition of patients with intermittent claudication may worsen when blood pressure becomes lower with Metoprolol Teva medication
- before undergoing surgery inform the doctor that you have this medication.

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

Certain concomitant medications can change the effect of Metoprolol Teva therapy or respectively Metoprolol Teva can change the effect of these concomitant medications. Therefore it is particularly important to tell the doctor of the use of the following medications:
- propafenone, amiodarone, quinidine, verapamil, diltiazem, clonidine, disopyramide and hydralazine, digitalis/digoxin (medicines for treatment of cardiovascular diseases)
- barbituric acid derivatives (antiepileptic medicines)
- anti-inflammatory medicines (for example indometacin and celecoxib)
- adrenaline (medicine used for treatment of acute shock and severe allergic reactions)
- phenylpropanolamine (medicine against the swelling of nasal mucosa)
- diphenhydramine (antiallergic medicine)
- terbinafine (medicine for treatment of fungal infections in the skin)
- rifampicin (medicine for treatment of tuberculosis)
- other beta blocking agents (for example eye drops)
- MAO inhibitors (antidepressants and medicines for treatment of Parkinson's disease)
- inhalation anaesthetics (agents used in anaesthesia)
- oral antidiabetics, Metoprolol Teva 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)
- cimetidine (antacid)
- antidepressants (paroxetine, fluoxetine and sertraline).

Metoprolol Teva with food and drink
Metoprolol Teva can be taken with or without food.

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.

<u>Pregnancy</u>
Metoprolol may only be used in pregnancy (particularly in the last 3 months) after the responsible doctor has precisely evaluated the benefits and risks. Metoprolol passes into the placenta and reduces perfusion of the placenta; this can damage the unborn child. Metoprolol should be discontinued 48-72 hours before the calculated time of birth. If this is not possible, the new born baby must be carefully monitored for 48-72 hours after the birth.

Breast feeding
Metoprolol passes into breast milk. Undesirable effects are not to be expected after therapeutic dosages. Breast fed babies should nevertheless be observed for possible drug effects.

Driving and using machines
Metoprolol Teva may in rare cases cause dizziness and tiredness and affect the ability to concentrate. So before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of Metoprolol Teva.

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

3. How to take Metoprolol Teva

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

The recommended dose is:

Adults:

- *High blood pressure:*
  50-100 mg once daily.

- *Angina pectoris:*
  100-200 mg once daily.

- *Heart failure in function class II:*
  For the first two weeks 25 mg once daily (initial dose).
  After two weeks the dose may be increased to 50 mg once daily and thereafter may be doubled on alternate weeks. The target dose for long-term treatment is 200 mg once daily.

- *Heart failure in function class III-IV:*
  For the first two weeks half a 25 mg tablet (corresponding to 12.5 mg) once daily (initial dose).
  After 1-2 weeks the dose may be increased to 25 mg once daily.
  After a further two weeks the dose may then be increased to 50 mg given once daily and thereafter may be doubled on alternate weeks up to 200 mg once daily for those patients who tolerate a higher dose.

- *Irregular heart beat with no organic cause:*
  100 mg once daily

- *Irregular heart beat:*
  100-200 mg once daily

- *Prophylactic treatment after an acute heart attack:*
  200 mg once daily

- *Prophylactic treatment for migraine:*
  100-200 mg once daily

Children and adolescents:

High blood pressure:
For children aged 6 years and older, the dose depends on the child’s weight. The doctor will work out

the correct dose for your child.
The usual start dose is 0.5 mg/kg once a day. The dose will be adjusted to the nearest tablet strength. Your doctor may increase the dose to 2.0 mg/kg once a day depending on blood pressure response. Doses above 200 mg once daily have not been studied in children and adolescents.
Metoprolol Teva prolonged-release tablets are not recommended for children under 6 years.

Method of administration
Metoprolol Teva prolonged-release tablets can be divided but not crushed or chewed and should be swallowed with a sufficient amount of liquid (at least half a glass).
Metoprolol Teva prolonged-release tablets provide a steady effect over the entire 24-hour period, and should therefore be taken once daily.
The tablet can be divided into equal doses.

If you take more Metoprolol Teva than you should
If you have taken a too high dose of a medicine, always contact a doctor, hospital or the Poison Information Centre for risk evaluation and to receive guidance.
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 Teva
If you forgot to take Metoprolol Teva, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue with your normal dosage schedule. You should check with your doctor or pharmacist if you are not sure.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Metoprolol Teva
Do not stop taking Metoprolol Teva without first discussing it with your doctor because certain symptoms (for example palpitation and angina pectoris) can worsen if the use of the medicine is discontinued abruptly.

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.

Very common (less than 1 in 10 but more than 1 in 100 patients):
Tiredness

Common (less than 1 in 10 but more than 1 in 100 patients):
Headache, dizziness, cold hands and feet, low pulse rate, palpitation, shortness of breath on exertion, stomach ache, nausea, vomiting, diarrhoea, constipation.

Uncommon (less than 1 in 100 patients but more than 1 in 1,000 patients):
Chest pain, weight gain, sleep disturbances, nightmares, lowered spirits, tingling in the skin, worsening of symptoms in the airways, transient impairment of heart failure. Blood pressure can decrease severely during a myocardial infarction, occurrence of hypersensitivity reactions in the skin such as redness or rash, oedema.

Rare (less than 1 in 1,000 patients but more than 1 in 10,000 patients):
Increased sweating, hair loss, changes in taste, transient impairment in sexual function, memory disturbances, confusion, nervousness, anxiety, hallucinations, worsening of psoriasis, hypersensitivity to sunlight, decrease in platelet count (thrombocytopenia), slowing of heart function, arrhythmias, liver

effects, visual disturbances, dry and irritated eyes, ringing in the ears (tinnitus).

Not known (frequency cannot be estimated from the available data):
Joint ache, inflamed liver, muscle cramps, dry mouth, allergic rhinitis (runny and stuffy nose), pinkeye (conjunctivitis), impairment of concentration, local tissue death (gangrene) in patients with severe circulatory disturbances.

Dry mouth can increase the risk of tooth decay, so regular and thorough brushing and dental care is important.

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 (see detail below). By reporting side effects you can help provide more information on the safety of this medicine.
[To be completed nationally]

5. How to store Metoprolol Teva

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

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater. 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 Teva contains

- The active substance is metoprolol succinate.
  Each tablet contains 23.75 mg, 47.5 mg, 95 mg or 190 mg metoprolol succinate equivalent to 25 mg, 50 mg, 100 mg or 200 mg of metoprolol tartrate.
- The other ingredients are
  Tablet core:
  Sugar spheres (containing sucrose and maize starch), macrogol, ethyl acrylate-methyl methacrylate copolymer, povidone, microcrystalline cellulose, magnesium stearate, silica (colloidal anhydrous).
  Tablet coating:
  Hypromellose, talc, macrogol, titanium dioxide (E 171).

What Metoprolol Teva looks like and contents of the pack

Metoprolol Teva 25 mg prolonged-release tablets
White, oblong, biconvex tablet with a break line on both sides (dimension: approx. 9.2 x 4.2 mm).
Metoprolol Teva 50 mg prolonged-release tablets
White, oblong, biconvex tablet with a break line on both sides (dimension: approx. 12.2 x 5.7 mm).
Metoprolol Teva 100 mg prolonged-release tablets
White, oblong, biconvex tablet with a break line on both sides (dimension: approx. 15.2 x 7.2 mm).
Metoprolol Teva 200 mg prolonged-release tablets
White, oblong, biconvex tablet with a break line on both sides (dimension: approx. 19.2 x 9.2 mm).

Blisters:
Metoprolol Teva 25 mg prolonged-release tablets are available in packs with 14, 28, 30, 50x1, 50, 56,

60, 90, 98, 100 prolonged-release tablets.
Metoprolol Teva 50 mg prolonged-release tablets are available in packs with 28, 30, 50x1, 50, 56, 60, 90, 98, 100 prolonged-release tablets
Metoprolol Teva 100 mg prolonged-release tablets are available in packs with 28, 30, 50x1, 50, 56, 60, 90, 98, 100 prolonged-release tablets
Metoprolol Teva 200 mg prolonged-release tablets are available in packs with 28, 30, 50, 56, 60, 90, 98, 100 prolonged-release tablets

Bottles:
Metoprolol Teva prolonged-release tablets are available in bottles with 30, 60, 100, 250 and 500 prolonged-release tablets.

(Not all pack sizes may be marketed.)

Marketing Authorisation Holder
<To be completed nationally>

Manufacturer
Merckle GmbH,
Ludwig-Merckle-Strasse 3,
D-89143 Blaubeuren, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark:	Metoprololsuccinat Teva
Finland, Slovakia:	Metoprolol ratiopharm
Sweden:	Metoprolol Teva

This leaflet was last approved
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