Package leaflet: Information for the user

Metocor 50 mg and 100 mg Tablets

Metoprolol tartrate

ROWEX®

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 Metocor is and what it is used for
2. What you need to know before you take Metocor
3. How to take Metocor
4. Possible side effects
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1 What Metocor is and what it is used for

Metocor contains a substance called metoprolol tartrate. Metoprolol tartrate 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).

Metocor is used for the treatment of:
- high blood pressure (hypertension)
- chest pain (angina pectoris)
- irregular or uneven heartbeats (cardiac arrhythmias)
- an overactive thyroid gland (hyperthyroidism) in combination with other medicines
- protect the heart in early treatment after a heart attack (myocardial infarction)
- long-term prophylaxis after recovery from a heart attack (to prevent another attack)
- preventing migraine.

2 What you need to know before you take Metocor

Do not take Metocor if:
- you are allergic to metoprolol tartrate, other beta-blockers or any of the other ingredients of this medicine (listed in section 6)
- you have heart failure which is not under control (this usually makes you breathless and causes your ankles to swell)
- you have or ever had a heart attack complicated by shock
- you suffer from other heart conditions:
  - sick sinus syndrome (malfunction of the sinus node causing abnormal heart rhythms)
  - second or third degree heart block (a condition which may be treated by a pacemaker)
  - severe bradycardia (very slow or uneven heartbeat)
  - low blood pressure (hypotension)
  - poor circulation (peripheral arterial disease)
- you are on therapy to improve your heart muscle contractions
- you feel faint (this may be due to very low blood pressure)
- you have severe asthma or COPD (chronic obstructive pulmonary disease)
- you are receiving other blood pressure lowering medicines such as verapamil and diltiazam by intravenous injection. See also "Other medicines and Metocor"
- you are using antiarrrhythmics such as disopyramide. See also "Other medicines and Metocor"
- you have a tumour called phaeochromocytoma that is not treated. This is usually near your kidney and can cause high blood pressure. If you are being treated for phaeochromocytoma your doctor will give you another medicine called an alpha-blocker, to take as well as your Metocor.
- you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).

You should first consult your doctor about these conditions.

Warnings and precautions:
The initial treatment of severe high blood pressure should be very gradual so as to avoid a sudden drop of blood pressure.

Talk to your doctor, pharmacist or nurse before taking Metocor if:
- you have asthma, wheezing or any other similar breathing problems
- you get allergic reactions, for example to insect stings or foods
- you have a type of chest pain (angina) called Prinzmetal's angina
- you have heart failure and one of the following:
  - had a heart 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
- you have poor blood circulation (in the fingers, toes, arms and legs)
- you have first degree heart block
- you have diabetes (your medicine may change how you respond to having low blood sugar)
- you have thyrotoxicosis (a condition caused by an overactive thyroid gland)
- you have symptoms of low blood sugar (hypoglycaemia)
- you have a skin rash or skin condition called psoriasis.

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

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 Metocor
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
This includes medicines that you buy without a prescription and herbal medicines. This is because Metocor can affect the way some other medicines work and some medicines can have an effect on Metocor. If Metocor 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, diclofenac (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, (for high blood pressure or migraine). If you are taking clonidine and Metocor together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give careful instructions about how to do it.
- 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
- Prazosin, tamsulosin, terazosine, doxazosin (alpha blockers, used to treat high blood pressure and benign prostatic hyperplasia)
- Lidocaine (local anaesthetic)
- Rifampicin (used to treat tuberculosis)
- Antacids (used for stomach upsets)
- Phenothiazines e.g. chlorpromazine.

Operations:
If you have a general anaesthetic at the dentist or in hospital, tell the anaesthetist or medical staff that you are taking Metocor.

Metocor with food, drink and alcohol
Metocor should be taken on an empty stomach. You are advised to avoid alcohol whilst taking this medicine. Alcohol and food when taken with Metocor may increase the effect of your medicine.

Pregnancy, breast-feeding and fertility:
Metoprolol 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:
- It is best to wait and see how your medicine affects you before trying to drive or use machines.
- If you feel dizzy or tired when taking this medicine, do not drive or use any tools or machines

Metocor contains lactose monohydrate:
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 Metocor

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Metocor should be taken without food and on an empty stomach.
- Metocor tablets can be divided into equal doses.
- Try to take your tablet at the same time each day.

Adults and Elderly people:
The recommended dose is:
- High blood pressure (hypertension): the usual dose is 100 mg to 200 mg daily as a single dose in the morning or a divided dose taken in the morning and evening. Doses usually start at 100 mg once daily. Doses up to 400 mg daily have been used.
- Chest pain (angina): the usual dose is 50 mg to 100 mg taken two or three times daily.
- Uneven heartbeats (arrhythmias): the usual dose is 50 mg two or three times daily. The dose may be increased up to 300 mg daily in divided doses. Treatment may start with an injection followed four to six hours later by 50 mg orally three times daily.
- Overactive thyroid gland (hyperthyroidism): the usual dose is 50 mg taken four times daily.
- The early treatment of a heart attack (myocardial infarction): Treatment may start with injections followed by 50 mg orally every six hours for two days. Your doctor may change this to 200 mg daily in divided doses.
- To help prevent migraine: the usual dose is 100 mg to 200 mg daily in divided doses (taken in the morning and evening).

Children:
Metocor must not be given to children.

People with severe liver problems:
If you have severe problems with your liver, your doctor may reduce your dose.

If you take more Metocor than you should:
- If you take more than the prescribed dose, or in the event of an overdose, talk to your doctor or go to a hospital straight away.
- If possible take the medicine pack with you so that the doctor knows what you have taken.

If you forget to take Metocor:
- Take your tablets as soon as you remember, then go on as before. Do not take more than the total daily dose in 24 hours.
- If it is almost time for the next dose, skip the missed dose
- Do not take a double dose to make up for the forgotten dose.

If you stop taking Metocor:
Do not suddenly stop taking Metocor even if you are feeling well, without talking to your doctor as this may cause worsening of heart failure and increase the risk of heart attack.

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Then only do so gradually. Your doctor will tell you how to do this. This is usually done over a period of 10 – 14 days, reducing the dose to 25 mg daily for the last 6 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.
The following side effects may happen with this medicine:

Stop taking Metocor and see a doctor or go to hospital straight away if you notice any signs of an allergic reaction. The signs may include raised lumps on your skin (wheals) or swelling of your face, lips, mouth, 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 tired, feeling faint on standing due to low blood pressure.

Common (may affect up to 1 in 10 people)
- your pulse rate may become slower. If this happens tell your doctor as soon as possible
- cold or poor blood circulation in your hands and feet
- postural disorders
- palpitations
- dizziness
- headache
- diarrhoea
- constipation
- stomach pain
- feeling sick (nausea)
- shortness of breath on exertion.

Uncommon (may affect up to 1 in 100 people):
- worsening of heart failure symptoms such as shortness of breath, tiredness or swollen ankles, during a heart attack blood pressure may severely decrease, heart block, swelling, chest pain
- sensation numbness or tingling
- muscle cramps
- being sick (vomiting)
- weight gain
- depression
- concentration impairment
- feeling sleepy or difficulty going to sleep
- nightmares
- feeling of tightness in the airways
- rash
- increased sweating.

Rare (may affect up to 1 in 1,000 people):
- disturbance of cardiac conduction
- irregular or uneven heartbeat (cardiac arrhythmias)
- dry mouth
- liver function test abnormalities
- nervousness
- anxiety
- unable to get an erection (impotence)
- Peyronie's syndrome (bending of penis on erection)
- runny nose
- problems with your eyesight (disturbances of vision)
- dry and/or irritated eyes
- watery/red eyes (conjunctivitis)
- hair loss
- worsening of diabetes.

Very rare (may affect up to 1 in 10,000 people)
- worsening of poor circulation in the extremities in patients with severe blood circulation disorders resulting in tissue death
- bruising more easily (due to a reduced number of platelets in your blood)
- hepatitis (inflammation of the liver)
- joint pain
- loss of memory/memory impairment
- feeling confused
- hallucinations
- ringing in the ears (tinnitus)
- taste disturbance
- skin reactions due to increased sensitivity to sunlight
- psoriasis (dry scaly skin condition) that may get worse when you start to take your medicine
- personality changes e.g. mood changes.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Metocor

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

Store in the original package.

Do not store above 30 °C.

Do not use this medicine after the expiry date which is stated on the carton and on each blister strip of tablets after ''Exp''. The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Metocor contains
The active substance is metoprolol tartrate.

Metocor 50 mg:
Each tablet contains 50 mg metoprolol tartrate
– The other ingredients are:
  Lactose monohydrate, maize starch, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, hyprolose, calcium hydrogen phosphate dihydrate and crospovidone.

Metocor 100 mg:
Each tablet contains 100 mg metoprolol tartrate.
– The other ingredients are:
  Lactose monohydrate, maize starch, microcrystalline cellulose, magnesium stearate, colloidal anhydrous silica, hyprolose, calcium hydrogen phosphate dihydrate and crospovidone.

What Metocor looks like and contents of the pack
Metocor 50 mg Tablets are white, round, biconvex tablets with a score notch on one side. The tablets can be divided into equal doses.

Metocor 100 mg Tablets are white, round, biconvex tablets with a score notch on one side. The tablets can be divided into equal doses.

Metocor 50 mg and 100 mg Tablets are blister packed and are available in sales packs of 100 tablets.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder:
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co Cork, Ireland.

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