

Metocor tablets

Metoprolol

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider 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, health care provider or pharmacist.

What is in this leaflet

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2. Before you take Metocor
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1. What Metocor is and what it is used for

Metoprolol is a beta-blocker that affects the heart and circulation (blood flow through arteries and veins).

Metoprolol is used to treat angina (chest pain) and hypertension (high blood pressure). It is also used to treat or prevent heart attack.

2. Before you take Metocor

Do not take Metocor:

- if you are allergic (hypersensitive) to metoprolol, or other beta-blockers (atenolol, carvedilol, labetalol, metoprolol, nadolol, nebivolol, propranolol, sotalol, and others), or any of the other ingredients of this medicine;
- a serious heart problem such as heart block, sick sinus syndrome, or slow heart rate
- severe circulation problems
- severe heart failure (that required you to be in the hospital);
- or history of slow heart beats that have caused you to faint

To make sure metoprolol is safe for you, tell your doctor if you have:

- asthma, chronic obstructive pulmonary disease (COPD), sleep apnea, or other breathing disorder
- diabetes (taking metoprolol may make it harder for you to tell when you have low blood sugar)
- liver disease
- congestive heart failure
- problems with circulation (such as Raynaud's syndrome)

- a thyroid disorder; or
- pheochromocytoma (tumor of the adrenal gland)

Use in children (under 18 years of age)

Do not give this medication to anyone under 18 years old without medical advice.

Due to the content of the wheat starch a drug should not be used in patients with celiac disease (gluten enteropathy).

This drug should not be taken in patients with rare genetic galactose intolerance manifested, Lapp lactase deficiency or glucose-galactose malabsorption

Taking other medicines, herbal or dietary supplements

Tell your doctor about all medicines you use, and those you start or stop using during your treatment with metoprolol, especially:

- bupropion
- prazosin
- terbinafine
- an antidepressant--bupropion, clomipramine, desipramine, duloxetine, fluoxetine, fluvoxamine, paroxetine, sertraline
- an ergot medicine--dihydroergotamine, ergonovine, ergotamine, methylergonovine
- heart or blood pressure medications--amlodipine, clonidine, digoxin, diltiazem, dipyridamole, hydralazine, methyldopa, nifedipine, quinidine, reserpine, verapamil, and others
- an MAO inhibitor--isocarboxazid, linezolid, phenelzine, rasagiline, selegiline, tranlycypromine; or
- medicine to treat mental illness--chlorpromazine, fluphenazine, haloperidol, thioridazine

This list is not complete. Other drugs may interact with metoprolol, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

Pregnancy and breast-feeding

Pregnancy

It is not known whether metoprolol will harm an unborn baby. Tell your doctor right away if you become pregnant while using this medication

Breast-feeding

Metoprolol can pass into breast milk and may harm a nursing baby. Tell your doctor if you are breast-feeding a baby.

Driving and using machines

Metoprolol may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

3. How to take Metocor

Always take Metocor exactly as your doctor or health care provider has told you. Your should check with your doctor, health care provider or pharmacist if you are not sure.

Metoprolol should be taken before meals or at bedtime.

- The dose for treating hypertension is 50-100 mg daily in single or divided doses (morning and evening).
- Angina is treated with 100-200 mg daily in two divided doses (morning and evening).
- **Heart attack** (acute myocardial infarction) is treated with 200 mg daily in two divided doses (morning and evening).
- The dose for Functional heart disorders, accompanied by tachycardia is 100 mg/daily in two divided doses (morning and evening).
- Hyperthyroidism is treated with 150 to 200 mg daily in 3-4 divided doses.

If you take more Metocor than you should

If you take more Metocor than prescribed, seek immediate medical attention.

Overdose symptoms may include slow or uneven heartbeats, shortness of breath, bluish-colored fingernails, dizziness, weakness, or fainting.

If you forget to take Metocor

If you forget to take a tablet, take the next dose at the right time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Metocor

Do not stop treatment with Metocor without consulting your doctor. Your doctor will determine the duration of treatment and how to discontinue it.

4. Possible side effects

Like all medicines, Metocor can cause side effects, although not everybody gets them.

The adverse reactions below are classified according to MedRA frequency and system organ class. The frequency grouping is defined using the following convention: Very common ($\geq 1/10$); Common ($\geq 1/100$ to $< 1/10$); Uncommon ($\geq 1/1,000$ to $< 1/100$); Rare ($\geq 1/10,000$ to $< 1/1,000$); Very Rare ($< 1/10,000$); and Not known (cannot be estimated from the available data).

Metoprolol is generally well tolerated. Side effects include abdominal cramps, diarrhea, constipation, fatigue, insomnia, nausea, depression, dreaming, memory loss, fever, impotence, lightheadedness, slow heart rate, low blood pressure, cold extremities, sore throat, and shortness of breath or whoezing. Metoprolol can aggravate breathing difficulties in patients with asthma, chronic bronchitis, or emphysema. In patients with existing slow heart rates (bradycardias) and heart blocks (defects in the electrical conduction of

the heart), metoprolol can cause dangerously slow heart rates, and even shock. Metoprolol reduces the force of heart muscle contraction and can aggravate symptoms of heart failure. In patients with coronary artery disease, abruptly stopping metoprolol can suddenly worsen angina, and occasionally precipitate heart attacks. If it is necessary to discontinue metoprolol, its dosage should be reduced gradually over several weeks.

5. How to store Metocor

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use this medicine after the expiry date which is stated on the pack. 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. Further information

What Metocor contains

- The active substance is Metoprolol. Each tablet contains 50 or 100 mg Metoprolol tartrate
- The other ingredients are: lactose monohydrate, wheat starch, cellulose, microcrystalline; povidone; talc, sodium starch glycolate, silica colloidal anhydrous, magnesium stearate.

What Metocor looks like and contents of the pack

Metocor is supplied as tablets.

Tablets 50 mg are white or almost white, round and flat.

Tablets 100 mg are white or almost white, round, flat with breakline.

Metocor 50 mg

15 tablets in blister of PVC/alu foil;

2 blisters with a patient information leaflet in a box

Metocor 100 mg

10 tablets in blister of PVC/alu foil;

3 blisters with a patient information leaflet in a box;

Marketing Authorisation Holder and Manufacturer

ADIPHARM EAD

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