

LEAFLET: INFORMATION FOR THE USER

Metoprolol tartrate Accord 50 mg and 100 mg Tablets (Metoprolol tartrate)

Read carefully the entire leaflet before you take this medicine because there contains important information in for you.

Keep this leaflet. You may need it later again ..

you have any questions? Then contact your doctor, or pharmacist.

Do not give this medicine to others , because it is only prescribed to you . It can be harmful harmful are for others, also even have they the same complaints as you.

Do you a lot of trouble with a of the side effects that in section 4 listed? Or do you get you a side effect that is not in this leaflet listed? Then contact your doctor, pharmacist.

Contents of this leaflet

1. What is Metoprolol tartrate Accord and for what is this medicine taken?
2. When may you this medicine not take or must be extra careful with be?
3. How do you take this medicine ? Possible
4. side effects How
5. do you store this medicine ? Contents?
6. Content of the packaging and other information

1. What is Metoprolol Tartrate Accord and what is this medicine used for?

Metoprolol is a selective beta-blocker. This means that metoprolol tablets the heart function influence and the blood pressure lower.

Metoprolol tartrate Accord Tablets are prescribed to patients:

to lower blood pressure to reduce;
with pain in the chest due to oxygen deficiency of the heart muscle (angina pectoris);
with disorders of the heart rhythm;
who a myocardial infarction have experienced; as protection against a possible subsequent myocardial infarction;
with palpitations;
with a too strong effect of the thyroid;
for prevention of migraine attacks.

2. When should you not take this medicine or should you take extra cautious with be?

When should you this medicine not take?

you are allergic (hypersensitive) to metoprolol, to other other beta-blockers of for one of the other substances that are in this medicine contain. These substances can you find under section 6.

if u heart conduction disorders or heart rhythm problems has (2nd or 3rd degree AVblock or 'sick sinus' syndrome (unless a permanent pacemaker is placed)).

if you untreated heart failure have, a treatment receive to contractions of the heart to allow increase or in shock are as result of heart problems.
if you suffers from severe blocked blood vessels, including problems with the circulation (causing your fingers and toes to tingle, or pale or blue become).
if you a slow heartbeat have (less than 50 beats/minute).
if you a low blood pressure have.
if suffer from a increased acid level of your blood (metabolic acidosis).
if you suffer from severe asthma or COPD (chronic obstructive pulmonary disease).
if you monoamine oxidase inhibitors use (MAOIs). See also 'Use with other medicines'.
if you heart failure have, and your blood pressure repeatedly below 100 mmHg falls.
if you other antihypertensive medications use, such as verapamil and diltiazem. See also 'Use with other medicines'.
if you medications against arrhythmias (anti-arrhythmics) used, such as disopyramide. See also 'Use with other medications'.
if you suffer from untreated pheochromocytoma (high blood pressure if result of a tumor of the adrenal medulla).

When should you be extra careful be with this medicine?

Contact your doctor or pharmacist before you this medicine take if you:

asthma have.
diabetes mellitus have (a low blood sugar level can by this medication masked be).
suffers from pheochromocytoma (high blood pressure as a result of a tumor of the adrenal medulla).
a treatment receives to allergic reactions to reduce. Metoprolol tablets can the sensitivity increase to the substances to which allergic to are, and the severity of the allergic reactions increase.
an overactive thyroid have (symptoms such as increased heart rate, sweating, trembling, anxiety, increased appetite or weight loss can by this medication be masked).psoriasis (severeskin rash skin rashhave or have had gehad).
if you receive anesthesia administered ;inform your doctor or dentist that you are using metoprolol tablets umetoprolol tablets suffers.
issues with the problems with the circulation (in the fingers, toes, arms and legs).
suffers from a heart conduction disorder (AV-block).
heart failure have in combination with a of the following factors:

- a heart attack or an attack of angina pectoris in the past 28 days.
- a reduced kidney- of liver function.
- younger are under 40 years or older than 80 years.
- disease of the heart valves.
- enlarged heart muscle.
- a heart surgery in the past 4 months.
- unstable heart failure (NYHA IV).

Use with other medicines

Do you besides metoprolol tartrate Accord still other medicines in, of has you that short ago done or exists the possibility that you in the near future other medications will take? Tell that then your doctor or pharmacist.

Do not use metoprolol tablets if you are already using one of the following medications ::

- Monoamine oxidase inhibitors (MAOIs) against a depression (these can the blood pressure-lowering effect enhance).
- other blood pressure-lowering agents, such as verapamil and diltiazem (these can a slow heartbeat or a stronger blood pressure drop cause).
- drugs against arrhythmias (anti-arrhythmics) such as disopyramide (this can the risk of an irregular or slow heartbeat increase and the heart function decrease).
- floctafenine (can the reactions of heart and blood vessels due to low blood pressure or shock reduce).
- sultopride (increased risk of an irregular heartbeat).

The following medicines can the effect on the blood pressure reduction enhance:

- cimetidine (for stomach ulcers).
- hydralazine and clonidine (antihypertensive agents).
- terbinafine (for fungal infections).
- paroxetine, fluoxetine and sertraline (against depressions).
- hydroxychloroquine (against malaria).
- chlorpromazine, triflupromazine, chlorprothixene (agents against psychoses).
- amiodarone, quinidine and propafenone (against an irregular heart rhythm).
- diphenhydramine (an antihistamine).
- celecoxib (for pain).

The following medicines can affect the blood pressure reduction reduce:

- indomethacin (against pain).
- rifampicin (an antibiotic).

Other medications that metoprolol can affect or be affected by metoprolol become:

- other beta-blockers, e.g.. eye drops.
- adrenaline (epinephrine), noradrenaline (norepinephrine) or other sympathomimetics.
- medicines for the treatment of diabetes; the symptoms of a low blood sugar level can be masked ..
- ..
- cardiac glycosides cardiac glycosides.

of metoprolol of metoprolol tablets with food and drink
Alcohol can the blood pressure-lowering effect of metoprolol tablets enhance.

Pregnancy and breastfeeding

Are you pregnant, think you pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your doctor or pharmacist before you use this medicine medication used.

Pregnancy

Your doctor can Metoprolol tartrate Accord prescribe during the pregnancy if the benefits of the use for you outweigh against the risks for the unborn child. If you Metoprolol tartrate

Accord have used until the delivery the will your newborn child possibly the first two days after the birth extra are monitored.

Breastfeeding

Metoprolol tartrate Accord is excreted via the breast milk. In normal dosages is the amount metoprolol in the breast milk small. Your child will extra be monitored.

Fertility

The data available indicate not not on particularities.

Driving ability and the use of machines

Metoprolol tablets can cause fatigue and dizziness . Make sure that you are aware of this no trouble with have before you go driving or operating machinery go use, especially if you switched to a different medication or if you have consumed alcohol have used.

3. How do you take this medicine ? Take

this medication always exactly as your doctor or your doctor or pharmacist you that has told. Doubt you about the correct use? Then contact your doctor or pharmacist.

The (whole or halved) tablets on one empty stomach take with a half glass water. Choose a fixed time.

The usual dosage is:

for high blood pressure: 100 or 200 mg (1-2 tablets), at preference once daily. Maximum 400 mg (4 tablets of 100 mg) per day.

for pain in the chest (angina pectoris): as needed depending the symptoms 100-200 mg (1-2 tablets of 100 mg) per day in divided doses. Maximum 400 mg (4 tablets of 100 mg) per day.

for disorders of the heart rhythm: 100-200 mg divided over the day (e.g.. two times daily 1 tablet of 50 mg). If necessary your doctor can increase the dosage further . if.

if protection against a next heart attack: twice daily 1 tablet of 100 mg.

for palpitations: 100 mg per day preferably once daily .. can your your doctor of dosage further increase to 200 mg (2 tablets of 100 mg) per day.

in a too strong effect of the thyroid: 150-200 mg divided over 3-4 doses per day (3-4 times daily 1 tablet of 50 mg). If necessary can your doctor dosage further increase ..

prevention of migraine attacks: 100-200 mg divided over 1-2 doses per over 1-2 doses per day (1-2 times daily 1 tablet of 100 mg).

The use of this medication will usually be long-term. Never change the dosage yourself or suddenly stop using the use.

In case of reduced kidney function: dose adjustment is not necessary.

In case of reduced liver function: inform your doctor if you a liver disease have. Possibly must the dosage adjusted be.

Elderly: dose adjustment is not necessary.

Children: the experience of this medication in children is limited.

The tablet can be divided into equal doses. Do

you you too much of this medicine taken?

If you have accidentally more than the prescribed dose have taken, contact the nearest emergency department or light immediately your doctor or pharmacist in.

Symptoms of an overdose are low blood pressure (fatigue and dizziness), slow pulse, irregular heart rhythm, cardiac arrest, shortness of breath, deep unconsciousness, nausea, vomiting and turning blue of the skin ..

Are you forgotten this medicine in to take?

If you your tablet(s) forgotten to take and you realize that within 4 4 hour after, then must you the forgotten tablet(s) as quickly as possible take and afterwards the next tablet(s) take according to your 'regular' schedule.

If it is longer than 4 hours ago that you should have taken your tablet(s) then skipthat dose and just wait until the next scheduled time to the time when you according to your 'regular' schedule the next tablet(s) should take ..

not double dose to to a missed dose in to catch up.

If you stop taking the taking of this medicine

If you suddenly stop taking the taking then can your condition suddenly deteriorate; there may arrhythmias or an increased blood pressure occur. The risk of a heart attack or of sudden death is increased.

The discontinuation of the treatment with metoprolol should therefore as a rule gradually be done and always in consultation with your doctor. During at least 2 weeks the dosage is gradually halved. The lowest dosage should at least 4 days taken to be before the treatment completely to stop.

When you during the tapering symptoms get, should you your doctor consult to seek.

4. Possible side effects

Like every medication can also this medication have side effects, although gets not everyone with that to deal.

Stop the treatment and take immediately contact with your doctor if you symptoms of a allergic reaction experiences, such as itchy skin rash, red becoming of the face, swelling of the face, the lips, the tongue or the throat, or problems with breathing or swallowing. This is a very

serious, but rare side effect. It may be that you urgently need medical assistance have of admitted must be in the hospital.

Tell the your doctor if you experience any of the following side effects or if you if you experience a side effect that is not listed in this leaflet ::

common (in more than 1 in 10 then 1 in 10 patients):	feel weak feel when standing up as a result of a low blood pressure, fatigue.
Often (in less than 1 in 10, but in more than 1 in 100 patients):	slow heartbeat, problems with maintaining balance (veryrarely with fainting),cold cold hands and feet, palpitations, dizziness, headache, nausea, diarrhea, constipation (constipation), abdominal pain, shortness of breath during physical exertion.
Sometimes (in less than 1 in 100, but in more than 1 in 1000 patients):	temporary worsening of the symptoms of heart failure, cardiac conduction disorders, retention of fluid, pain in the chest, tingling sensation, muscle cramps, vomiting, weight gain, depression, reduced concentration, insomnia, drowsiness, nightmares, shortness of breath, skin rash, increased sweating.
Rarely (in less than 1 in 1000, but in more than 1 in 10,000 patients):	worsening of diabetes, nervousness, anxiety, visual disturbances, dry or irritated eyes, conjunctivitis, impotence, syndrome of Peyronie (curvature of the penis during an erection), irregular heartbeat, dry mouth, runny nose, hair loss, changes in the liver function tests.
Very rarely (in less than 1 in 10,000 patients):	changes in the blood cells, forgetfulness, confusion, hallucinations, mood swings, tinnitus, hearing problems, taste changes, inflammation of the liver (hepatitis), sensitivity to light, onset or exacerbation of psoriasis, muscle weakness, joint pain, necrotic tissue in patients with severe disorders in the circulatory system.

The reporting of side effects

Do you experience side effects, please contact your doctor or pharmacist. This applies also to possible side effects that are not in this leaflet .You can side effects also directly report via the Dutch Side Effects Centre Lareb (www.lareb.nl). By reporting side effects ,you can help us gain more information on obtain about the safety of this medication.

Do you a lot suffer from one of the side effects? Or do you a side effect that not in this leaflet states? Contact your doctor or pharmacist.

5. How do you store this medicine Keep out of

sight and reach of from children keep.

Do not store above 25°C.

Store your tablets in the original packaging.

Do not use this medicine after the expiry the expiry date. It is to find on the box after EXP. There is a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or the toilet and do not throw them away in the trash. Ask your pharmacist what you should do with medicines must do that you no longer use. They are then in a responsible manner destroyed and do not enter the environment in the environment justified.

6. Contents of the package and other information


Which substances are in this medicine?

The active ingredient in this medicine is metoprolol tartrate 50 mg and 100 mg.

The other ingredients in this medicine are microcrystalline cellulose (E460), gelatin (E441), sodium starch glycolate, colloidal hydrated silicon dioxide (E551), stearic acid (vegetable) (E477).

How do Metoprolol tartrate Accord Tablets look and what is in a package

50 mg tablets – white to off-white, round, biconvex tablet with the imprint  on the one side and a score line on the other side

100 mg tablets – white to off-white, round, biconvex tablet with the imprint  on the one side and a score line on the other side

Metoprolol tartrate Accord Tablets are packaged in blister packs. The box contains 30, 60 or 90 tablets. Not all mentioned pack sizes are on the market ..

of the license for for the in the trade bringing

Accord Healthcare B.V., Winthontlaan 200, 3526 KV Utrecht

Manufacturer

Accord Healthcare Polska Sp.z o.o., ul. Lutomierska 50,95-200 Pabianice, Poland

Registered under number:

Metoprolol tartrate Accord 50 mg Tablets, RVG 57170.

Metoprolol tartrate Accord 100 mg Tablets, RVG 57171.

This leaflet is last approved in November 2021. November 2021.