

Package leaflet: Information for the patient

Betablockade 50 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.

What is in this leaflet:

1. What Betablockade is and what it is used for
2. What you need to know before you take Betablockade
3. How to take Betablockade
4. Possible side effects
5. How to store Betablockade
6. Contents of the pack and other information

1. What Betablockade is and what it is used for

Betablockade belongs to a group of medicines known as beta-blockers.

Betablockade is used in the treatment of:

- high blood pressure;
- tightening chest pain caused by insufficient oxygen supply to the heart (angina pectoris);
- irregular heart beat (arrhythmia);
- heart attack;
- palpitations (feeling your heart beat) caused by functional heart disorders.

It is used in the prevention of:

- another heart attack;
- migraine attacks.

2. What you need to know before you take Betablockade

Do not take Betablockade and tell your doctor:

- If you are allergic to metoprolol or other beta-blockers, such as any of the other ingredients of this medicine (listed in section 6);
- If you have heart problems (2nd or 3rd degree atrioventricular block) or abnormal heart rhythm (sick sinus syndrome);
- If you are suffering from untreated heart disease or you are either being treated for increased heart contractions or you are in shock caused by heart problems;
- If you have circulation disorders;
- If you have bradycardia (slow heart rate of less than 50 beats per minute);
- If you have low blood pressure;
- If you have a metabolic acidosis;
- If you have severe asthma or COPD (chronic obstructive pulmonary disease);
- If you have untreated pheochromocytoma of adrenal glands;

- If you suffer from heart failure and your blood pressure stays below 100 mm Hg.

If you are taking any of the following medicines:

- monoamine oxidase (MAO) inhibitors (for depression);
- verapamil and diltiazem (medicines lowering blood pressure);
- antiarrhythmic medicines such as disopyramide.

Warnings and precautions

- if you have bronchial asthma;
- If you have Prinzmetal's angina (acute chest pain that occurs more often at night);
- If you have diabetes, as metoprolol may mask the symptoms of hypoglycaemia (low blood sugar);
- If you have pheochromocytoma (a benign tumor of the adrenal gland that causes an increase in blood pressure);
- If you are being treated to reduce an allergic reaction. Betablockade may increase your hypersensitivity to the substances you are allergic to and increase the severity of allergic reactions.
- If you suffer from overactive thyroid gland (symptoms such as fast heartbeat, sweating, tremor, anxiety, increased appetite or weight loss may be covered by this medicine.).
- If you suffer or have suffered from psoriasis (a severe skin condition).
- If you have problems with blood circulation, which may cause numbness, paleness or bruising of the fingers and toes;
- • If you have heart failure or suffer from any of the following conditions:
 - If you suffer from acute heart failure (NYHA IV functional class)
 - If you have had a heart attack or angina in the last 28 days
 - If you have reduced kidney and liver function
 - If you are under 40 or over 80 years of age
 - If you suffer from heart valve disease
 - If you suffer from an increase in the size of the heart muscle
 - If you have had heart surgery in the last 4 months

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking metoprolol, as your heart beat might slow down too much.

Children and adolescents

Always use Betablockade in children and adolescents exactly as instructed by your doctor.

Other medicines and Betablockade

Do not take Betablockade if you are taking:

- monoamine oxidase (MAO) inhibitor for depression;
- Other medicines that lower blood pressure, such as verapamil and diltiazem, as they may slow down your heart rate or cause your blood pressure to drop too much.;
- Antirhythmics, such as disopyramide (may increase the risk of heart rhythm disturbance or slowing and weakening of the heart).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following medications may increase the effect of lowering blood pressure:

- cimetidine (medicines used to treat ulcers);
- Hydralazine and clonidine (antihypertensive);
- terbinafine (antifungal medicine);
- Paroxetine, fluoxetine and sertraline (antidepressants);
- hydroxychloroquine (antimalarial drug);

- chlorpromazine, triflupromazine, chlorprothixene (antipsychotics);
- amiodarone, chinidin and propafenone (antirhythmics);
- diphenhydramine (antihistamines);
- celecoxib (painkiller);

The following medications may reduce the effect of lowering blood pressure:

- indomethacin (painkiller);
- rifampicin (antibiotic).

Other drugs that may affect or be affected by metoprolol are:

- other beta-blockers (e.g. eye drops);
- adrenaline (epinephrine), noradrenaline (norepinephrine) or other sympathomimetics;
- medicines to treat diabetes because the symptoms of low blood sugar can be suppressed;
- lidocaine;
- reserpine, alpha-methyldopa, guanfacine, cardiac glycosides.

Betablockade with food, drink and alcohol

Drinking alcohol during treatment with metoprolol may increase the effects of this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Betablockade can make you feel dizzy or tired. Please make sure that you are not affected before driving or using machines, especially at the beginning of treatment, when increasing the dose, after changing the medicine or taking alcohol at the same time..

3. How to take Betablockade

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

Generally, Betablockade should be taken once daily in the morning, with glass of water. Betablockade tablets (or halves of tablets) must not be chewed or crushed.

The usual dose is:

- **High blood pressure:**

50 mg Betablockade once daily. If necessary, the dose can be increased to 100-200 mg.

- **Angina pectoris:**

100-200 mg Betablockade once daily.

- **Cardiac arrhythmias**

100-200 mg once daily.

- **Prevention of subsequent heart attack:**

200 mg Betablockade once daily.

- **Functional heart disorders with palpitations:**

The recommended dose is 100 mg once daily. If necessary, your doctor may increase the dose to

200 mg once daily.

- **Prevention of migraine:**

100-200 mg Betablockade once daily.

- **Symptomatic chronic heart failure:**

Always follow the instructions of your doctor.

Patients with impaired liver function

If you have severe liver problems, your doctor will determine the dose you need. Always follow your doctor's instructions.

If you take more Betablockade than you should

If you take more Betablockade than you should, contact your doctor immediately or go to the emergency department of your nearest hospital. Symptoms of severe overdose are low blood pressure (fatigue and dizziness), slow pulse, slow or irregular heart rate, cardiac arrest, задых, complete unconsciousness (comma), feeling sick, being sick and cyanosis.

If you forget to take Betablockade

When you miss your Betablockade dose take your dose as soon as possible if less than 12 hours have passed since your scheduled dose. Do not take a double dose to make up for the forgotten tablet. Take the next dose at the indicated time.

If you stop taking Betablockade

Do not stop taking Betablockade suddenly, as this may make your disease worse and increase your risk of heart attack. You can change the dose or stop the treatment only after consulting your doctor.

If you have any further questions on the use of this product, 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 the following symptoms of an: allergic reaction such as itching, difficulty breathing or swelling of the face, lips, throat or tongue. These are very rare but also very serious side effects that may require emergency medical care or hospital admission.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed.

Very common ($\geq 1/10$):

- dizziness;
- tiredness.

Common ($\geq 1/100$ to $< 1/10$):

- a slow heart rate;
- feeling faint on standing due to low blood pressure;
- cold limbs;
- dizziness;
- headache;
- nausea, diarrhoea, constipation, stomach pain;
- shortness of breath during physical exercise;

- palpitations.

Uncommon ($\geq 1/1\ 000$ to $< 1/100$):

- temporary worsening of the symptoms of heart failure;
- fluid retention (swelling);
- chest pain;
- burning, tingling or numbness of limbs;
- muscle cramps;
- vomiting;
- weight gain.;
- depression;
- concentration disorders;
- insomnia;
- somnolence;
- nightmares;
- difficulty breathing;
- skin rash;
- swelling.

Rare ($\geq 1/10\ 000$ to $< 1/1\ 000$)

- worsening of diabetes;
- nervousness, anxiety;
- vision disorders;
- dry and (or) irritated eyes,;
- conjunctivitis;
- sexual dysfunction or reduced sex drive;
- irregular heartbeat;
- dry mouth;
- rhinitis;
- hair loss;
- changes in liver function tests.

Very rare ($< 1/10\ 000$):

- blood disorders (decreased number of platelets and leukocytes in the blood);
- memory loss or impairment;
- confusion;
- hallucinations;
- changes in mood;
- ringing in the ears;
- hearing problems;
- taste disorders;
- hepatitis;
- sensitivity to light;
- worsening of psoriasis;
- muscle weakness;
- joint pain;
- gangrene in patients with severe poor circulation.

Reporting of side effects

Reporting of suspected adverse reactions after authorization of the medicinal product is important. This allows the benefit / risk balance for the medicinal product to be monitored.

Medical professionals are required to report any suspected adverse reactions through a national reporting system to the Bulgarian Drug Agency.

Contacts:

Bulgarian Drug Agency
8 Damyan Gruev Str.,
1303 Sofia.
Tel.: +359 2 890 3417
Website: www.bda.bg

5. How to store Betablockade

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

The product does not require special storage conditions.
Do not use this medicine after the expiry date which is stated on the carton/blister after EXP.
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. Съдържание на опаковката и допълнителна информация

What Betablockade contains

- The active substance is metoprolol succinate. Each prolonged-release tablet contains: - 47,5 mg metoprolol succinate equivalent to 50 mg metoprolol tartarate.
- The other ingredients are:
 - *Core*: microcrystalline cellulose, methylcellulose, corn starch, glycerol, ethyl cellulose and magnezium stearate.
 - *Coating*: Sepifilm®LP 770: hypromellose, microcrystalline cellulose, stearic acid, titanium dioxide.

What Betablockade looks like and contents of the pack

Each carton contains 30 tablets Betablockade 50 mg.

Marketing Authorisation Holder and Manufacturer

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria

For any information about this medicine, please contact the Marketing Authorization Holder:

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria
tel.: 02 / 962 54 54
fax: 02/ 960 37 03
e-mail: info@tchaikapharma.com

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