Package leaflet: Information for the user

Bloxazoc 25, 23,75 mg prolonged-release tablets
Bloxazoc 50, 47,5 mg prolonged-release tablets
Bloxazoc 100, 95 mg prolonged-release tablets
Bloxazoc 200, 190 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 Bloxazoc is and what it is used for

Metoprolol succinate belongs to a group of medicines called beta-blockers. Metoprolol reduces the effect of stress hormones on the heart during physical and mental effort. It leads to the heart to beat more slowly (heart rate decreases) in these situations.

Bloxazoc is used to **treat**:
- high blood pressure (hypertension),
- a tight pain in the chest caused by insufficient oxygen to the heart (angina pectoris),
- irregular heart rhythm (arrhythmia),
- palpitations (feeling your heart beat) due to non-organic (functional) heart disorders,
- stable heart failure with symptoms (such as shortness of breath or swollen ankles), when taken together with other medicines for heart failure.

Bloxazoc is used to **prevent:**
- further heart attacks or damage to the heart after a heart attack,
- migraine.

Bloxazoc is used to treat high blood pressure in children and adolescents aged 6 - 18 years.

2. What you need to know before you take Bloxazoc

Do not take Bloxazoc:
- if you are allergic to active substance, other beta-blockers or any of the other ingredients of this medicine (listed in section 6),
- if you have unstable heart failure, are receiving treatment to increase heart contractions,
- if you have heart failure and your blood pressure keeps falling below 100 mmHg,
- if you have a slow heart rate (less than 45 beats/min) or low blood pressure (hypotension),

- if you are in shock caused by heart problems,
- if you have heart conduction problems (2nd or 3rd degree atrioventricular block) or heart rhythm problems (sick sinus syndrome),
- if you suffer from severe blood circulation problems (severe peripheral arterial disease).

Warnings and precautions
Talk to your doctor or pharmacist before taking Bloxazoc.
- if you recieve verapamil intravenously
- if you suffer from blood circulation problems which may cause your fingers and toes to tingle or turn pale or blue
- if you have tight chest pain usually occurring during the night (Prinzmetal's angina)
- if you have asthma or other chronic obstructive lung diseases
- low blood sugar levels may be hidden by this medicine (diabetes mellitus)
- if you suffer from a heart conduction disorder (heart block)
- if you are having treatment to reduce allergic reactions. Bloxazoc may increase your hypersensitivity to the substances you are allergic to and increase the severity of allergic reactions
- if you have high blood pressure due to a rare tumour in one of your adrenal glands (phaeochromocytoma)
- if you have heart failure
- if you are going to have an anaesthetic please tell your doctor or dentist that you are taking metoprolol tablets
- if you suffer from increased acidity of the blood (metabolic acidosis),
- if you have severely impaired renal function
- if you are being treated with digitalis.

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

The following medicines can increase the effect on lowering blood pressure:
- propafenone, amiodarone, quinidine, verapamil, diltiazem, clonidine, disopyramide and hydralazine, digitalis / digoxin (a medicine for cardiovascular disease),
- barbituric acid derivatives (antiepileptic drug),
- medicines for inflammation (e.g., indomethacin and celecoxib),
- adrenalin (drug in acute shock and severe allergic reaction),
- phenylpropanolamine (medicines to mucous membranes in the nose),
- diphenhydramine (medicines for allergic conditions),
- terbinafine (for fungal infection),
- rifampicin (an antibiotic),
- other beta-blockers (e.g. eye drops),
- MAO inhibitors (used to treat depression and Parkinson's disease),
- inhalation anesthetics (drugs for anesthesia),
- medicines used to treat diabetes, the symptoms of low blood sugar may be hidden,
- cimetidine (a medicine for heartburn and acid regurgitation),
- paroxetine, fluoxetine, and sertraline (medicines for depression).

Bloxazoc with food, drink and alcohol
Bloxazoc can be taken with or without food.

Pregnancy and breast-feeding
Beta-receptor blockers (including metoprolol) may decrease heart rate in the foetus and in the new-born infant. Bloxazoc 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
Bloxazoc may make you feel tired and dizzy. Make sure you are not affected before you drive or operate machinery, particularly after changing to another medicine or if taken with alcohol.

3. How to take Bloxazoc

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

Bloxazoc prolonged-release tablet is a dosage form that provides a uniform effect through the day and is to be taken once daily with a glass of water in the morning.
Bloxazoc 25 mg prolonged-release tablet can be divided into equal doses.
Bloxazoc 50 mg, 100 mg, 200 mg prolonged-release tablet can be halved: for ease of swallowing and not to divide into equal doses.
Bloxazoc tablets (or the divided halves) should not be chewed or crushed. They should be swallowed with liquid.

Usual doses:
High blood pressure (hypertension):
47.5-95 mg metoprolol succinate (50-100 mg metoprolol tartrate) once daily.

Tight chest pain (angina pectoris):
95-190 mg metoprolol succinate (100-200 mg metoprolol tartrate) once daily.

Irregular heart beats (arrhythmia):
95-190 mg metoprolol succinate (100-200 mg metoprolol tartrate) once daily.

Preventive therapy following a heart attack.
190 mg metoprolol succinate (200 mg metoprolol tartrate) once daily.

Palpitations due to heart disease:
95 mg metoprolol succinate (100 mg metoprolol tartrate) once daily.

Prevention of migraine:
95-190 mg metoprolol succinate (100-200 mg metoprolol tartrate) once daily.

Patients with stable heart failure in combination with other medications:
The starting dose is 11.88-23.75 mg metoprolol succinate (12.5-25 mg metoprolol tartrate) once daily. The dose can be increased gradually as needed to a maximum 190 mg metoprolol succinate (200 mg metoprolol tartrate) once daily.

Patients with impaired liver function:
If you have **severely** impaired liver function your doctor may adjust the dose. Always follow your doctor's advice.

Use in children and adolescents
Bloxazoc is not recommended for children under 6 years. Always use Bloxazoc for children and adolescents exactly as your doctor has told you.
The doctor will calculate the dose that is right for your child. The dosage depends on the weight of the child.
The recommended starting dose for high blood pressure is 0.48 mg/kg metoprolol succinate (0.5 mg/kg metoprolol tartrate) once daily (half a tablet of Bloxazoc 25 mg for a child weighing 25 kg). The dose will be adjusted to the nearest tablet strength. In patients not responding to 0.5 mg/kg metoprolol tartrate, the dose can be increased to 0.95 mg/kg metoprolol succinate (1.0 mg/kg metoprolol tartrate), not exceeding 50 mg metoprolol tartrate. In patients not responding to 1.0 mg/kg

metoprolol tartrate, the dose may be increased to 1.9 mg/kg metoprolol succinate (2 mg/kg metoprolol tartrate) once daily (1 tablet of Bloxazoc 50 mg for a child weighing 25 kg). Doses above 190 mg metoprolol succinate (200 mg metoprolol tartrate) once daily have not been studied in children and adolescents.

If you take more Bloxazoc than you should
If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist at once.

If you forget to take Bloxazoc
If you forget to take a dose, take it as soon as you remember, then go on as before.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Bloxazoc
Do not suddenly stop taking Bloxazoc as this may cause worsening of heart failure and increase the risk of heart attack. Only change the dose or stop the treatment in consultation with your doctor.

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 (may affect more than 1 in 10 people):
- tiredness.

Common (may affect up to 1 in 10 people):
- headache, dizziness,
- cold hands and feet, slow heartbeat, palpitations,
- shortness of breath with strenuous physical activity,
- feeling sick, abdominal pain, vomiting, diarrhoea, constipation.

Uncommon (may affect up to 1 in 100 people):
- depression, nightmares, difficulty in sleeping,
- pins and needles,
- transient worsening of symptoms of heart failure,
- during a heart attack, blood pressure may be greatly reduced, cardiogenic shock in patients with acute myocardial infarction
- shortness of breath worsening of bronchial problems,
- hypersensitivity reactions of the skin,
- chest pain, fluid retention (swelling), weight gain.

Rare (may affect up to 1 in 1,000 people):
- changes in blood cells counts (thrombocytopenia),
- forgetfulness, confusion, hallucinations, nervousness, anxiety,
- taste changes,
- visual disturbances, dry or irritated eyes,
- heart conduction disturbances, heart rhythm disturbances,
- changes in liver function tests,
- worsening or new psoriasis (a type of skin disease), sensitivity to light, increased sweating, hair loss,
- impotence (inability to obtain an erection),
- ringing in the ears.

Not known (frequency cannot be estimated from the available data):

- impaired concentration,
- muscle cramps,
- eye inflammation,
- tissue death in patients with severe blood circulation problems,
- runny nose,
- dry mouth,
- inflammation of the liver (hepatitis),
- joint pain.

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 via www.ravimiamet.ee . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bloxazoc

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

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

Do not store above 30°C.

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. Contents of the pack and other information

What Bloxazoc contains
- The active substance is metoprolol succinate.
  - Each prolonged-release tablet contains 23.75 mg metoprolol succinate equivalent to 25 mg metoprolol tartrate.
  - Each prolonged-release tablet contains 47.5 mg metoprolol succinate equivalent to 50 mg metoprolol tartrate.
  - Each prolonged-release tablet contains 95 mg metoprolol succinate equivalent to 100 mg metoprolol tartrate.
  - Each prolonged-release tablet contains 190 mg metoprolol succinate equivalent to 200 mg metoprolol tartrate.
- The other ingredients are silica, colloidal anhydrous; cellulose, microcrystalline; hypromellose; sodium laurilsulfate; polysorbate 80; glycerol; hydroxypropylcellulose; ethylcellulose; and sodium stearyl fumarate in the tablet core and hypromellose; titanium dioxide (E171); talc and propylene glycol in the film coating.

What Bloxazoc looks like and contents of the pack

25 mg: white to almost white, oval, biconvex, film coated tablets with score line on one side of the tablet (dimension 8.5 mm x 4.5 mm). On one side of the score line mark C is engraved on the other side of the score line mark 1 is engraved.

50 mg: White to almost white, oval, slightly biconvex, film coated tablets with score line on one side of the tablet (dimension 10.5 mm x 5.5 mm). On one side of the score line mark C is engraved on the other side of the score line mark 2 is engraved.

100 mg: White to almost white, oval, biconvex, film coated tablets with score line on one side of the

tablet (dimension 13 mm x 8 mm). On one side of the score line mark C is engraved on the other side of the score line mark 3 is engraved.

200 mg: White to almost white, biconvex, capsule shaped film coated tablets with score line on both sides of the tablet (dimension 19 mm x 8 mm). On one side of the tablet on one side of the score line mark C is engraved on the other side of the score line mark 4 is engraved.

Bloxazoc is available in boxes containing 10, 14, 28, 30, 50, 56, 60, 84, 90, 98 and 100 tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

or

TAD Pharma GmbH,
Heinz-Lohmann-Straße 5
27472 Cuxhaven
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

KRKA, d.d., Novo Mesto Eestonian branch
Pärnu mnt 141
11314 Tallinn
Phone: +372 6671658

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