

Patient Information Leaflet
(PIL)
CarelioTM 25/50/100/200 mg Retard Tablets

Metoprolol

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. 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 or pharmacist. See section 4.

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1. WHAT CARELIO IS AND WHAT IT IS USED FOR?

The active substance in Carelio is metoprolol. Metoprolol belongs to the group of medicines called beta-blockers and is used for the treatment of high blood pressure (hypertension), the long term treatment of angina pectoris (tightness in the chest), chronic heart failure (chronic cardiac insufficiency), heart rhythm disorders and cardiovascular disorders with palpitations, as well as for the prevention of migraine.

Due to its special formulation, which allows controlled release of the active substance, the effect of Carelio prolonged-release tablets usually lasts 24 hours.

Carelio may be taken only when prescribed by a doctor and with ongoing medical monitoring.

2. BEFORE YOU TAKE CARELIO

When must Carelio not be used?

Carelio must not be taken if you have a known hypersensitivity to the active substance metoprolol, to any of the other ingredients or to any other medicines that belong to the group called beta-blockers.

In addition, Carelio must not be taken:

- if you have problems with the passage of electrical impulses from the heart's upper chambers (atria) to the lower chambers (ventricles) (2nd- and 3rd-degree AV block),
- if you have an irregular heartbeat which is often very slow and sometimes very fast (except if you have a permanent pacemaker),

- if you have problems with the passage of electrical impulses between the sinus node and upper chamber of the heart (atrium),
- if you are suffering from shock,
- if you have a weak heart together with fluid accumulation in the lungs, poor blood circulation or low blood pressure,
- if your resting pulse rate before treatment is less than 50 beats per minute,
- if you have abnormally low blood pressure,
- if the circulation in your arms or legs is severely reduced,
- if you are prone to bronchial asthma or bronchial spasms.

When caution is needed while taking Carelio?

This medicine may affect your reactions, your ability to use tools and machinery and your ability to drive.

If you are taking other medicines for breathing disorders at the same time, the dosages of the various medicines must be readjusted by a doctor.

Caution is advised in case of diabetes mellitus, certain heart conditions, heart conduction disorders, circulatory disorders, impaired liver function as well as in patients with a hormone-producing tumour (phaeochromocytoma).

Before surgery the anaesthetist should be informed that you are taking Carelio .

Some medications (including nose and eye drops) as well as alcohol may interfere with the action of Carelio if taken at the same time.

Tell your doctor or pharmacist if you suffer from other illnesses, have any allergies or are taking any other medicines (including those purchased without a prescription).

May Carelio be taken during pregnancy or breast feeding?

If you are pregnant or intend to become pregnant, or if you are breast feeding, consult your doctor before taking Carelio .

Carelio , a beta-blocker, may harm the foetus or induce premature labour.

3. HOW TO TAKE CARELIO

Carelio prolonged-release tablets are taken once daily with a glass of water. They can be taken with or without meals. The Carelio prolonged-release tablets have a score line and can be easily divided. However, they must not be crushed or chewed.

The doctor will prescribe the right dose for you based on regular tests/examinations. In general, the following dosage guidelines apply:

High blood pressure (hypertension)

Adults

In cases of mild to moderate high blood pressure, take 1 prolonged-release tablet of Carelio 50, once daily in the morning. The dosage may be increased by the doctor to 1 prolonged-release tablet of Carelio 100 or Carelio 200. If necessary, your doctor may prescribe an additional blood-pressure lowering medicine for you.

Children and adolescents (6 to 16 years of age)

For children from 6 years of age, the dosage depends on body weight. Your doctor will determine the correct dosage for your child and monitor it regularly.

The use of Carelio by children below 6 years of age is not recommended.

Angina pectoris (tightness in the chest)

In cases of angina pectoris, take 1 prolonged-release tablet of Carelio 100 or Carelio 200 once daily. If necessary, your doctor may increase the dose.

Chronic heart failure (chronic cardiac insufficiency)

In cases of chronic heart failure, the initial dose is Carelio 25 mg once daily for 2 weeks.

In cases of severe heart failure, the doctor may prescribe you a lower initial dose of 12.5 mg once daily (half a Carelio 25 mg prolonged-release tablet). The dose can then be doubled every two weeks up to 200 mg Carelio once daily.

Heart rhythm disorders

In cases of heart rhythm disorders, take 1 prolonged-release tablet of Carelio 100 or Carelio 200 once daily. If necessary, your doctor may increase the dose.

Cardiovascular disorders with palpitations

In cases of cardiovascular disorders, take 1 prolonged-release tablet of Carelio 100 once daily. If necessary, your doctor may increase the dose.

Prevention of migraine

For the prevention of migraine, take 1 prolonged-release tablet of Carelio 100 or Carelio 200 once daily.

You must not stop taking Carelio suddenly. The doctor will decide how to reduce the dose gradually.

Do not change the prescribed dosage yourself. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

The following side effects may occur when taking Carelio :

Very common: tiredness. Common: dizziness, headache, nausea, abdominal pain, shortness of breath, abnormally slow pulse, cold hands and feet, diarrhoea and constipation.

Uncommon: exhaustion, vomiting, pain around the heart, oedema (water retention in the tissues), muscle cramps, drowsiness, sleeplessness, nightmares, impaired concentration, depression, increased sweating, rash, asthma attacks and weight gain. Rare: palpitations, irregular heartbeat, heart failure, nervousness, anxiety, visual disturbances, dry and irritated eyes, inflammation of the lining of the nose, muscle weakness, dry mouth, hair loss, libido disorders and erectile dysfunction.

Very rare: mood swings, impaired memory, confusion, hallucinations, ringing in the ears, taste disturbances, sensitivity of the skin to light, worsening of psoriasis and joint pain.

If you notice any side effects not described here, you should tell your doctor or pharmacist.

5. HOW TO STORE CARELIO

Do not store above 25°C and keep out of the sight and reach of children.

This medicine may be used only up to the date marked with “EXP” on the pack. If you have out-of-date medication, return it to the pharmacy for disposal.

Further information may be obtained from your doctor or pharmacist. These persons have the detailed prescribing information at their disposal.

6. FURTHER INFORMATION

a. What Carelio contains

1 prolonged-release tablet of Carelio 25, 50, 100 and 200 contains 23.75 mg, 47.5 mg, 95 mg and 190 mg respectively of metoprolol succinate, equivalent to 25 mg, 50 mg, 100 mg and 200 mg respectively of metoprolol tartrate.

b. What Carelio looks like and contents of the pack

Packs of 30, 50 and 100 prolonged-release tablets are available (Carelio 25, Carelio 50, Carelio 100, Carelio 200).

c. Marketing Authorisation Holder and Manufacturer

Acino Pharma AG, Liesberg (Switzerland)

d. This leaflet was last revised by the medicines authority (Swissmedic) in March 2015.

e. To report any side effects:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

By reporting side effects you can help provide more information on the safety of this medicine

f. Council of Arab Health Ministers

**This is a
Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health
Ministers Union of Arab
Pharmacists