

Betaloc[®] CR

Metoprolol succinate, 23.75 mg, 47.5 mg, 95 mg, 190 mg controlled release tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Betaloc CR**. It does not contain all the information that is known about **Betaloc CR**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Betaloc CR** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Betaloc CR is used for

Betaloc CR belongs to a group of medicines called beta-blockers. It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It also widens the blood vessels in the body, as well as helping the heart to beat more regularly.

Betaloc CR is a controlled release tablet that releases its drug content in a time controlled manner. Controlled release tablets ensure a more even effect over 24 hours.

Betaloc CR tablets are used for:

- lowering high blood pressure, also called hypertension, to reduce the risk of complications due to high blood pressure such as stroke, heart attack or early death.
- preventing angina (heart or chest pain brought on by stress or exercise in patients with coronary heart disease).
- treating or preventing heart attacks, or to reduce your risk of heart complications following a heart attack.
- treating heart failure (symptomatic mild to severe chronic heart failure in addition to other heart failure medicine), to help increase survival, reduce hospitalisation, improve symptoms, and quality of life.
- treating disturbances of heart rate in patients with heart disease, especially rapid heart beat.
- treating symptoms of rapid or irregular heart beat in patients without heart disease.
- prevention of migraine headaches.
- overactive thyroid (hyperthyroidism).

Your doctor may have prescribed this medicine for another reason. Your doctor will have explained why you are being treated with **Betaloc CR** and told you what dose to take.

Betaloc CR may be used either alone or in combination with other medicines to treat your condition.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why **Betaloc CR** has been prescribed for you.

Betaloc CR is not addictive

Betaloc CR is only available with a doctor's prescription.

Before you use Betaloc CR***When you must not use it***

1. **if you have or have had asthma (difficulty in breathing, wheezing and coughing), bronchitis or other lung problems in the past.**
2. **If you have the following conditions:**
 - a history of allergic problems, including hay fever
 - a very slow heart beat
 - a severe blood vessel disorder causing poor circulation in the arms and legs
 - certain other heart conditions.
3. **Do not take Betaloc CR tablets if you are pregnant or intend to become pregnant or if you are breast-feeding unless your doctor says to do so.**

As with all medicines used to lower blood-pressure, metoprolol may cause unwanted effects, e.g. slow heart rate, in the foetus and in the new-born baby. Beta-blockers including metoprolol may cause harm to the foetus and early labour. You should tell your doctor as soon as possible if you become pregnant while using **Betaloc CR**. The risk of any effect of using **Betaloc CR** on the baby, if you are breast-feeding is low if the mother is taking doses within the normal recommended dose range for treatment.

Do not use Betaloc CR if the expiry date (EXP) printed on the pack has passed. It may have no effect at all, or worse, an entirely unexpected effect if it is used after the expiry date.

Do not use Betaloc CR if the packaging is torn or shows signs of tampering.

Do not give Betaloc CR to children. The safety and effectiveness of **Betaloc CR** in children has not been established.

Before you start to take it

You must tell your doctor if:

1. **you have any allergies to**
 - **Betaloc CR** or any of the ingredients listed at the end of this leaflet.
 - any other medicine or other beta-blocker medicines
 - any other substances, such as foods, preservatives or dyes
 - insect stings.
2. **you have any other health problems relating to your**
 - lungs
 - liver
 - kidneys or adrenal glands
 - heart
 - blood circulation

Also tell your doctor if you have diabetes and / or if you have had symptoms of low blood sugar (hypoglycaemia).

If you have not told your doctor about any of these things, tell them before you take Betaloc CR.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- Medicines used in the treatment of heart and blood vessels (such as digitalis/digoxin, calcium antagonists, antiarrhythmic agents, sympathetic ganglion blockers, hydralazine).
- Other medicines such as monoamine oxidase (MAO) inhibitors, inhalation anaesthetics, antibacterial medicines (rifampicin), antiulcer medicines (cimetidine), anti-inflammatory medicines (indomethacin, celecoxib), certain antidepressants and antipsychotic medicines, antihistamines, other beta-blockers (including eye drops) and other substances (alcohol, some hormones).
- If you take clonidine and Betaloc CR at the same time and your clonidine treatment is to be discontinued, Betaloc CR should be withdrawn several days before clonidine.
- If you take an oral antidiabetic, your doctor may need to adjust your dose.
- Medicines that you buy without a prescription at the chemist, supermarket or health food shop.

These medicines may be affected by **Betaloc CR** or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor if you have recently taken any medicines that you buy or use without a prescription such as herbal remedies, health foods or supplements.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **Betaloc CR**.

If you have not told your doctor about any of these things, tell them before you take any **Betaloc CR**.

How to use Betaloc CR

Betaloc CR tablets should be swallowed with liquid. The tablets and the divided halves should not be chewed or crushed (see What **Betaloc CR** Looks Like). Generally **Betaloc CR** is recommended to be taken once a day together with the morning meal. Your doctor will tell you how much **Betaloc CR** you need to take. Take the dose your doctor prescribes so that you get full benefit from this medicine.

How much to take

For high blood pressure:

Adults: The recommended dose in patients with mild to moderate high blood-pressure is 47.5 mg taken once a day. If you do not adequately respond to 47.5 mg, your doctor may increase the dose to 90-190 mg once a day or combine **Betaloc CR** with other medicines.

Long term treatment with **Betaloc CR** in daily doses of 95-190 mg has been shown to reduce the risk of complications due to high blood-pressure (stroke, myocardial infarction, sudden cardiac death).

Children: Betaloc CR tablets are not recommended for children under 6 years. For children aged 6 years and older, the dose depends on the child's weight. Your doctor will work out the correct dose for your child.

For angina pectoris:

The recommended dose is 95-190 mg taken once a day. Your doctor may prescribe **Betaloc CR** with other medicines used for treatment of angina pectoris.

Maintenance treatment after myocardial infarction:

The usual dose for patients treated for a long time is 190 mg taken once a day. Long term treatment with **Betaloc CR** in daily doses of 190 mg has been shown to reduce the risk of death and to reduce the risk of reinfarction.

Heart Failure

The recommended starting dose is 23.75 mg or half a 23.75 mg tablet once daily during the first one to two weeks. It is then recommended to double the dose every second week up to a maximum dose of 190 mg once daily or the highest tolerated dose.

Disturbances of cardiac rhythm:

The recommended dose is 95-190 mg taken once a day.

Functional heart disorders with palpitations:

The recommended dose is 95 mg taken once a day. If necessary, your doctor may increase the dose to 190 mg.

For migraine prevention or hyperthyroidism:

The recommended dose is 95-190 mg taken once a day.

Do not stop taking Betaloc CR tablets suddenly. The dose needs to be reduced slowly over 7 to 14 days to make sure that your condition does not get worse.

Follow your doctor's instructions carefully.

If you forget to take it

If you miss a dose of **Betaloc CR** and your next dose is about 12 hours away, take the missed dose, or half of it right away. If you remember sooner, take the full dose but if it is closer to your next dose, take only half. Then, take your next dose on time. **Do not take a double dose to make up for the dose that you missed.** If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Betaloc CR***Things you must do***

Be sure to keep all of your doctor's appointments so that your progress can be checked.

If you become pregnant while taking Betaloc CR, tell your doctor.

If your heartbeat becomes slower and slower when taking Betaloc CR, inform your doctor as soon as possible. The doctor may give you a lower dose of Betaloc CR or withdraw your medicine gradually. You may feel light-headed or dizzy when you begin to take **Betaloc CR**. This is because your blood pressure has fallen suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you feel a worsening of your condition in the early stages of taking Betaloc CR.

Some people may experience an apparent worsening of their condition in the early stages of treatment with **Betaloc CR**. It is important to tell your doctor if this happens to you, although it is usually temporary. If your condition continues to worsen, you should see your doctor as soon as possible.

Make sure you drink enough water during exercise and hot weather when you are taking Betaloc CR, especially if you sweat a lot. If you do not drink enough water while taking **Betaloc CR**, you may feel faint or light-headed or sick. This is because your blood pressure is dropping too much. If you continue to feel unwell, tell your doctor.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking **Betaloc CR**. Your blood pressure may drop suddenly if **Betaloc CR** interacts with the anaesthetic.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

If you have to have any medical tests while you are taking **Betaloc CR**, tell your doctor. **Betaloc CR** may affect the results of some tests.

Tell any doctors, dentists, and pharmacists who are treating you that you are taking **Betaloc CR**.

Things you must not do

Do not stop taking Betaloc CR without checking with your doctor. Your doctor may want you to gradually reduce the amount of **Betaloc CR** you are taking before stopping completely. If possible this should be done over at least 2 weeks. Doses should be reduced to half a 23.75 mg tablet once a day for at least 4 days before stopping completely. This may help reduce the possibility of your condition getting worse.

Do not give Betaloc CR to anyone else even if they have the same condition as you.

Do not use Betaloc CR to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how **Betaloc CR** affects you. As with other beta-blocker medicines, **Betaloc CR** may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to **Betaloc CR** before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Be careful drinking alcohol while you are taking Betaloc CR. Dizziness or light-headedness may be worse.

Overdose

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Betaloc. Even if there are no signs of discomfort or poisoning.

If you take too many **Betaloc CR** tablets your blood pressure may drop too far. You will feel faint, or lose consciousness, and your heart rate will also slow down. You may also have nausea, vomiting and convulsions. In extreme cases, serious heart and lung problems may occur.

The first signs of overdosage may be observed 20 minutes to 2 hours after you have taken the medicine. If you experience any of these symptoms contact your doctor/pharmacist or hospital immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Betaloc CR. Tell your doctor if any of the following side effects bother you or continue.

Very common

- tiredness (fatigue)

Common

- dizziness
- headache
- slow heart rate
- dizziness related to change of position of the body

- cold hands and feet
- feeling sick (nausea)
- stomach ache
- diarrhoea
- constipation
- shortness of breath on effort
- feeling of heart pounding in the chest.

Uncommon

- sensation of burning/ prickling/ numbness
- muscle cramps
- symptoms of heart disease such as shortness of breath
- fatigue or swollen ankles may temporarily worsen
- during a heart attack blood pressure may be severely decreased (cardiogenic shock)
- minor ECG changes which do not affect heart performance
- swelling
- chest pain
- depression
- concentration impaired
- feeling sleepy
- difficulty going to sleep
- nightmares
- skin rash
- feeling of tightness in the airways
- being sick (vomiting)
- increased sweating
- weight gain

Rare

- disturbances of cardiac conduction in the ECG
- irregular heart beat
- nervousness
- anxiety
- liver problems (liver function test abnormalities)
- hair loss, runny nose due to allergic reaction
- disturbances of vision
- dry and/or irritated eyes
- dry mouth
- watery/red eyes due to allergic reaction
- impotence/sexual dysfunction

Tell your doctor if you notice anything else that is making you feel unwell or bothering you.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Betaloc CR**.

After using Betaloc CR

Storage

Keep your tablets in the blister pack until it is time to take them. If you take **Betaloc CR** out of the blister pack it will not keep well. **Keep the tablets in a cool dry place where the temperature stays below 30°C.** Do not store it or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines. **Keep it where young children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. **Do not leave it in the car on hot days.**

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What Betaloc CR looks like

Betaloc CR 23.75 mg is white, to off-white, oval with a size of 5.5 mm x 10.5 mm, scored on both sides and marked A/β on one side. The tablet can be divided into two equal doses.

Betaloc CR 47.5 is white to off-white, circular with a diameter of 9 mm, scored on one side and marked A/mo on one side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Betaloc CR 95 mg is white to off-white, circular with a diameter of 10 mm, scored on one side and marked A/ms on one side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Betaloc CR 190 mg is white to off-white, oval with a size of 8.5 mm x 17 mm, scored on one side and marked A/my on one side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Ingredients

Each **Betaloc CR** tablet contains:

Metoprolol succinate 23.75 mg, 47.5 mg, 95 mg or 190 mg as the active ingredient,

Plus ethylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, microcrystalline cellulose, paraffin, polyethylene glycol, silicon dioxide, sodium stearyl fumarate, titanium dioxide.

Marketed by:

AstraZeneca Limited
PO Box 87453, Meadowbank
Auckland 1742
Telephone: (09) 306 5650.

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