Patient information leaflet

SCHEDULING STATUS

S3

BETACOR 5 film-coated tablet

BETACOR 10 film-coated tablet

Bisoprolol fumarate

Read this entire leaflet carefully before you start taking BETACOR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BETACOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BETACOR is and what it is used for

BETACOR contains the active substances bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers.

BETACOR is indicated for the management of mild to moderate hypertension and angina pectoris.

2. What you need to know before you take BETACOR

Do not take BETACOR:

- If you are allergic to Bisoprolol fumarate or any of the other ingredients of BETACOR (listed in section 6).
- If you have severe asthma
- If you have severe blood circulation problem in limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
- If you have untreated phaeochromocytoma, which is a rare tumour of the adrenal gland (medulla).
- If you have metabolic acidosis, which is a condition when there is too much acid in the blood.
- If you have heart failure
- If you have very low blood pressure.
- If you have certain heart condition causing a very slow heart rate or irregular heartbeat.
- If you have cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

Warnings and precautions

Do not stop BETACOR therapy abruptly, especially if you have coronary heart disease as this may lead to transitional worsening of your heart condition.

Use BETACOR with special care if:

- You have sugar diabetes as symptoms of hypoglycaemia (e.g. palpitations or sweating) may be masked.
- You are fasting
- You are receiving ongoing desensitisation therapy. BETACOR may increase both the sensitivity to allergens and the severity of anaphylactic reactions.
- You have first degree AV block
- You have Prinzmetal's angina
- You are undergoing general or regional anaesthesia - inform your doctor
- You suffer from psoriasis
- You have a thyroid disorder

In addition, tell your doctor:

- If you have ever suffered from gout, as BETACOR may enhance the risk for gout attacks;
- If you are going to have anaesthesia (e.g. for surgery) because BETACOR may influence how your body reacts to this situation;
- If you plan to have desensitisation therapy, because BETACOR may make it more likely that you experience an allergic reaction, or such a reaction may be more severe;

If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using BETACOR.

Children and adolescents

Safety and efficacy of BETACOR have not been established in children.

Other medicines and BETACOR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of BETACOR with these medicines may cause undesirable interactions. Such medicines include:

- Medicines that lower blood glucose.
- Medicines used for emotional or psychiatric conditions e.g. phenothiazines.
- Medicines that correct the rhythm of your heart.
- Medicines that stimulate or suppress your nervous system.
- Certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (known as Calcium antagonists of the verapamil type).
- Certain medicines used to treat high blood pressure such as clonidine, methyldopa etc. However, do not stop taking these without checking with your doctor first.
- Certain medicines used to treat irregular or abnormal heartbeat. Medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainides propafenone, amiodarone.
- Certain medicines used to treat high blood pressure or angina pectoris (known as Calcium antagonists of the dihydropyridine type (e.g. nifedipine).
- Parasympathomimetics medicines such as acetylcholine, methacholine, carbachol.
- Topical application of beta-blockers such as eye drops for treatment of glaucoma.
- Insulin and oral mediation used to treat diabetes
- Anaesthetic agents, (for example during surgery)
- Digoxin used to treat heart failure.
- Non-steroidal anti-inflammatory medicines, used to treat arthritis, pain or inflammation.

- Beta-sympathomimetics (e.g. dobutamine, isoprenaline)
- Sympathomimetics such as epinephrine and norepinephrine which are used in the treatment of heart attack and low blood pressure. Epinephrine is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for treatment of allergic reactions if BETACOR is taken at the same time.
- Any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives, certain medicines for depression (tricyclic antidepressants), certain medicines used to treat epilepsy or during anaesthesia (barbiturates), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines).
- Mefloquine, used for prevention or treatment of malaria.
- Depression treatment medicines called monoamine oxidase inhibitors).

BETACOR with food and drink

BETACOR may be taken with or without food but must be taken in the morning.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BETACOR.

BETACOR is not recommended during pregnancy and breastfeeding.

Driving and using machines

The ability to drive or operate machinery may be affected, depending on how well you tolerate the medicine. Be especially careful at the beginning of the treatment, when the dose is increased or when the medication is changed, and when combined with alcohol.

Bisoprolol may cause dizziness or fatigue (see ADVERSE EFFECTS) and, therefore, may adversely affect your ability to drive or use machinery.

3. How to take BETACOR

Do not share medicines prescribed for you with any other person.

Always use BETACOR exactly as your doctor has instructed you. Your doctor will decide which dose is applicable to you. You should check with your doctor or pharmacist if you are unsure.

The recommended dosage is one tablet (BETACOR 5 mg) once daily.

If necessary, the dosage may be increased to two tablets (BETACOR 5 mg) once daily.

The maximum recommended dosage is 20 mg once daily.

The film-coated tablets are to be swallowed whole with some liquid in the morning before, during or after breakfast.

BETACOR is not indicated for use in children.

BETACOR therapy should not be stopped abruptly.

Your doctor will tell you how long your treatment with BETACOR will last.

If you take more BETACOR than you should

If you take more BETACOR than your normal dose, contact your doctor or nearest hospital immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison information centre.

If you forget to take BETACOR

Do not take a double dose to make up for a forgotten dose, please consult your doctor.

If you stop taking BETACOR

BETACOR therapy should not be stopped abruptly.

If you have the impression that the effect of BETACOR is too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.

4. Possible side effects

BETACOR can cause side effects.

Not all side effects reported for BETACOR are included in this leaflet. Should your general health worsen while taking BETACOR, please consult your doctor, pharmacist or other health care professional for advice.

Frequent side effects are:

- Dizziness, headache
- Gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation
- Feeling of coldness or numbness in the hands and feet
- Fatigue (tiredness)
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- Fatigue (tiredness)

Less frequent side effects are:

- Palpitations, worsening of pre-existing heart failure
- Irregular heartbeats
- Tightening of the chest in patients with bronchial asthma

- Slow pulse rate
- Muscle weakness, muscle cramps
- Depression, sleep disorders, numbness or muscle weakness
- Hypotension, low blood pressure
- Reduced tear flow, visual disturbances
- Hearing disorders
- Allergic rhinitis, runny, itchy nose and ears
- Hypersensitivity reactions (itching, flush, rash). You should see your doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.
- Hepatitis
- Problems with erections
- Nightmares, hallucinations
- Fainting
- Increase in liver enzymes
- Conjunctivitis (pink eye)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s

publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BETACOR.

5. How to store BETACOR

Store all medicines out of the reach of children.

Store at or below 30 °C. Store in the original package in order to protect from light.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What BETACOR contains

The active ingredient is bisoprolol fumarate.

The other ingredients are calcium hydrogen phosphate, maize starch, silica colloidal anhydrous, cellulose microcrystalline, crospovidone, magnesium stearate, hypromellose, macrogol, dimethicone, iron oxide, titanium dioxide.

What BETACOR looks like and contents of the pack

BETACOR 5 are yellowish white, heart-shaped biconvex film-coated tablets with dividing score on both sides.

BETACOR 10 are pale-orange light orange, heart-shaped biconvex film-coated tablets with dividing score on both sides.

BETACOR is available in blister packs containing 30 tablets.

Holder of Certificate of Registration

Merck (Pty) Ltd

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Name and address of the manufacturer

Merck Healthcare KGaA

250 Frankfurterstrasse, 64293 Darmstadt, Germany

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TBD

Registration numbers

BETACOR 5 tablets:	38/5.2/0080
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