

BETALOC[®] TABLETS

Metoprolol tartrate

Consumer Medicine Information

What is in this leaflet

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

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 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 is used for

BETALOC belongs to a group of medicines called beta-blockers.

BETALOC tablets are used to:

- lower high blood pressure, also called hypertension
- prevent angina
- treat or prevent heart attacks, or reduce your risk of heart complications following a heart attack
- prevent migraine headaches.

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.

Your doctor will have explained why you are being treated with BETALOC and told you what dose to take.

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

Ask your doctor if you have any questions about why BETALOC has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

BETALOC is not addictive

Before you take BETALOC

When you must not take it

Do not take BETALOC tablets if:

- **You have any allergies to metoprolol tartrate, the active ingredient in BETALOC tablets, or any of the ingredients listed at the end of this leaflet, or any other beta-blocker medicine.**

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or

hives on the skin or you may feel faint.

- **you have asthma, wheezing, difficulty breathing or other lung problems, or have had them in the past**
- **you have a history of allergic problems, including hayfever**
- **you have low blood pressure**
- **you have a very slow heartbeat (less than 45-50 beats/minute)**
- **you have certain other heart conditions**
- **you have phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines**
- **you have a severe blood vessel disorder causing poor circulation in the arms and legs**
- **you are receiving/having emergency treatment for shock or severely low blood pressure.**

If you are not sure whether any of these apply to you, check with your doctor.

Do not use BETALOC if the expiry date (EXP) printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not give BETALOC to children.

The safety and effectiveness of BETALOC in children has not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you have any allergies to:

- metoprolol tartrate or any of the ingredients listed at the end of this leaflet.
- any other medicine, including other beta-blocker medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- asthma, wheezing, difficulty breathing or other lung problems
- diabetes
- an overactive thyroid gland
- liver problems
- kidney problems
- certain types of angina
- any other heart problems
- phaeochromocytoma, a rare tumour of the adrenal gland
- any blood vessel disorder causing poor circulation in the arms and legs.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most beta-blocker medicines, BETALOC is not recommended for use during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

The active ingredient in BETALOC passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and BETALOC may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops.
- calcium channel blockers or calcium antagonists, medicines used to treat high blood pressure and angina, for example verapamil and diltiazem
- medicines used to treat high blood pressure, for example clonidine, hydralazine, and prazosin
- medicines used to treat abnormal or irregular heartbeat, for example amiodarone, disopyramide and quinidine
- medicines used to treat arthritis, pain, or inflammation, for example indomethacin and ibuprofen
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- medicines used to treat diabetes
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to treat bacterial infections, for example rifampicin
- medicines used to treat depression
- monoamine-oxidase inhibitors (MAOIs).

These medicines may be affected by BETALOC 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.

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

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

How to take BETALOC

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

For high blood pressure:

The usual starting dose is one 50mg or 100mg tablet once a day for one week.

The dose is then usually increased to 50mg or 100mg once or twice daily.

Your doctor may tell you to take a different amount of BETALOC.

Follow your doctor's instructions carefully.

If you are taking other prescription medicines which lower blood pressure, your doctor may need to change the dose of them to obtain the best results for you.

For angina pectoris:

The usual dose is 50mg or 100mg taken two or three times a day.

After myocardial infarction (heart attack):

The usual dose is 100mg taken twice a day, often starting with a lower dose for 2 days.

For migraine prevention:

The usual dose is 100-150 mg a day, taken in divided doses morning and evening.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

How to take it

Swallow the tablet with a glass of fluid.

When to take BETALOC

Take your medicine at about the same time each day before or after food.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take BETALOC

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it.

It is important to keep taking your medicine even if you feel well.

DO NOT STOP TAKING BETALOC TABLETS SUDDENLY.

The dose needs to be reduced slowly over 7 to 14 days to make sure that your condition does not get worse. Your doctor will tell you how to gradually reduce the dose before stopping completely.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

Telephone your doctor, the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much BETALOC. Do this even if there are no signs of discomfort or

poisoning. You may need urgent medical attention.

If you take too many BETALOC tablets your blood pressure may drop too far. You will feel faint or faint, 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.

While you are using BETALOC

Things you must do

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

Elderly patients especially need to be monitored to stop their blood pressure falling too far.

If you become pregnant while taking BETALOC, tell your doctor immediately.

If you have a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that BETALOC may cause allergic reactions to be worse and harder to treat.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take BETALOC. 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.

Make sure you drink enough water during exercise and hot weather when you are taking BETALOC, especially if you sweat a lot.

If you do not drink enough water while taking BETALOC, 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 are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

BETALOC may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar (hypoglycaemia). BETALOC may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicines, including insulin, may need to change.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BETALOC.

Tell any doctors, dentists, and pharmacists who are treating you that you are taking BETALOC.

If you plan to have surgery (even at the dentist) that needs an anaesthetic, tell your doctor or dentist that you are taking BETALOC.

If you have to have any medical tests while you are taking BETALOC, tell your doctor.

BETALOC may affect the results of some tests.

Things you must not do

Do not stop taking BETALOC without checking with your doctor.

Your doctor may want you to gradually reduce the amount of BETALOC you are taking before stopping completely. This may help reduce the possibility of your condition getting worse.

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

Do not use BETALOC 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 affects you.

As with other beta-blocker medicines, BETALOC may cause dizziness, light-headedness, tiredness, or drowsiness in some people. Make sure you know how you react to BETALOC 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.

If you drink alcohol, dizziness or light-headedness may be worse.

Dress warmly during cold weather, especially if you will be outside for a long time (for example when playing winter sports).

BETALOC, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have circulation problems.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BETALOC.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache, tiredness, drowsiness, weakness, or lack of energy
- aches and pains, painful joints
- nausea (feeling sick), vomiting

- stomach upset, diarrhoea or constipation, weight gain
- dry mouth, changes in taste sensation
- difficulty sleeping, nightmares
- mood changes
- confusion, short-term memory loss, inability to concentrate
- increased sweating, runny or blocked nose
- hair loss

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- dizziness, lightheadedness or fainting especially on standing up, which may be due to low blood pressure.
- tingling or "pins and needles"
- coldness, burning, numbness or pain in the arms and/or legs
- skin rash or worsening of psoriasis
- sunburn happening more quickly than usual
- abnormal thinking or hallucinations
- buzzing or ringing in the ears, deafness
- irritated eyes or blurred vision
- sexual problems
- constant "flu-like" symptoms with tiredness or lack of energy
- unusual bleeding or bruising.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, being less able to exercise
- swelling of the ankles, feet or legs
- chest tightness, wheezing, noisy breathing, difficulty breathing
- chest pain, changes in heart rate or palpitations

- swelling of the face, lips, tongue or throat which may cause difficulty swallowing or breathing
- yellowing of the skin or eyes (jaundice), generally feeling unwell.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed here may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take BETALOC 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. Do not leave it in the car or on a window sill.

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.

Disposal

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

Product description

What BETALOC looks like

BETALOC 50 mg tablets are white to off-white, circular with a diameter of 8 mm, scored and marked A/BB on one side. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

BETALOC 100 mg tablets are white to off-white, circular with a diameter of 10 mm, scored and marked A/ME on one side. The tablet can be divided into equal halves by breaking along the score line.

Ingredients

Each BETALOC tablet contains:

Metoprolol tartrate 50mg or 100mg as the active ingredient,

plus

- Lactose monohydrate
- Microcrystalline cellulose
- Colloidal anhydrous silica
- Sodium starch glycollate
- Povidone
- Magnesium stearate (E 572)

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Sponsor

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Australian Registration Number

Betaloc 50mg - Aust R 12065

Blister pack of 100 tablets

Betaloc 100mg - Aust R 12384

Blister pack of 60 tablets