

BETALOC(R) 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 for

BETALOC 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 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

Your doctor may have prescribed this medicine for another reason.

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.

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 has been prescribed for you.

BETALOC is not addictive

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

Do not give BETALOC to children.

The safety and effectiveness of BETALOC 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 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

- 2. you have any of these medical conditions**

- * asthma

- * diabetes

- * an overactive thyroid gland

- * liver problems

- * kidney problems

- * certain types of angina

- * any other heart problems

- * phaeochromocytoma

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

Before you take BETALOC

When you must not take it

Do not take BETALOC tablets if:

- 1. you are pregnant or intend to become pregnant**

BETALOC may affect your baby if you are given it early in pregnancy or in the last weeks before your baby is due.

- 2. you are breast-feeding or plan to breast-feed**

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

Taking other medicines

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

- * other beta-blocker medicines, including beta-blocker eye drops.
- * medicines used to treat high blood pressure or angina
- * medicines used to treat heart problems
- * insulin and tablets used to treat diabetes
- * medicines used to treat depression
- * medicines that you buy without a prescription at the chemist, supermarket or health food shop.

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.

Taking BETALOC

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:

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 50mg to 75mg taken twice a day (100-150mg a day).

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.

If you forget to take it

If it is almost time for your next dose (within 6 hours), 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 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.

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

Your blood pressure may drop suddenly if BETALOC 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.

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

BETALOC may affect the results of some tests.

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

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.

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.

- * 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 or nurse immediately if you notice any of the following:

- * dizziness, lightheadedness or fainting especially on standing up
- * tingling or "pins and needles"
- * 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

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 or nurse immediately:

- * shortness of breath, being less able to exercise,
- * swelling of the ankles, feet or legs
- * chest tightness, wheezing, noisy breathing
- * chest pain, changes in heart rate or palpitations
- * swelling of the face, lips, tongue or throat.
- * yellowing of the skin or eyes (jaundice), generally feeling unwell.
- * constant "flu-like" symptoms with tiredness or lack of energy

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

Some people may get other side effects while being given BETALOC.

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 degrees 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.

The 50mg tablet is marked A/BB and is slightly smaller than the 100mg tablet which is marked A/ME.

Ingredients

Each BETALOC tablet contains:

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

plus

Lactose

Cellulose - microcrystalline (E 460)

Silica - colloidal anhydrous

Sodium starch glycollate

Povidone

Magnesium stearate (E 572)

Manufacturer

AstraZeneca Pty Ltd

ABN 54 009 682 311

Alma Road

NORTH RYDE NSW 2113

Australian Registration Number

Betaloc 50mg

Blister pack of 100 tablets

Aust R 12065

Betaloc 100mg

Blister pack of 60 tablets

Aust R 12384

This leaflet was prepared in November 2006.

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Product description

What BETALOC looks like

BETALOC tablets are white, biconvex, circular, scored and marked on one side.