BETALOC® TABLETS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BETALOC tablets?

BETALOC tablets contains the active ingredient metoprolol tartrate. 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 or to prevent migraine headaches.

For more information, see Section 1. Why am I using BETALOC tablets? in the full CMI.

2. What should I know before I use BETALOC tablets?

Do not use if you have ever had an allergic reaction to BETALOC or any of the ingredients listed at the end of the CMI, if 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 or if you are receiving/having emergency treatment for shock or severely low blood pressure.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use BETALOC tablets? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BETALOC tablets and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use BETALOC tablets?

- BETALOC tablets are available as either 50 mg or 100 mg tablets. The dose of BETALOC tablets depends on what condition you are being treated for. Your doctor will tell you what dose to take.
- Swallow the tablet with a glass of fluid.

More instructions can be found in Section 4. How do I use BETALOC tablets? in the full CMI.

5. What should I know while using BETALOC tablets?

Things you should do	• Remind any doctor, dentist, or pharmacist you visit that you are using BETALOC. • Be sure to keep all of your doctor's appointments so that your progress can be checked. • If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. • Make sure you drink enough water during exercise and hot weather when you are taking BETALOC, especially if you sweat a lot. • If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.
Things you should not do	• Do not stop using this medicine suddenly without checking with your doctor.
Looking after your medicine	• Keep your tablets in the blister pack until it is time to take them.

For more information, see Section 5. What should I know while using BETALOC tablets? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience side effects, most of them are minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

BETALOC® TABLETS

Active ingredient(s): *metoprolol tartrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BETALOC tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BETALOC tablets.**

Where to find information in this leaflet:

1. Why am I using BETALOC tablets ?
2. What should I know before I use BETALOC tablets ?
3. What if I am taking other medicines?
4. How do I use BETALOC tablets ?
5. What should I know while using BETALOC tablets ?
6. Are there any side effects?
7. Product details

1. Why am I using BETALOC tablets?

BETALOC tablets contains the active ingredient metoprolol tartrate. 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.

2. What should I know before I use BETALOC tablets?

Warnings

Do not use BETALOC tablets if:

- **you are allergic to metoprolol tartrate, 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.

Check with your doctor if you:

- are not sure whether any of the above apply to you
- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children and adolescents

Do not give BETALOC to children.

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

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

3. What if I am taking other medicines?

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

Some medicines may interfere with BETALOC and affect how it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BETALOC tablets.

4. How do I use BETALOC tablets?

How much to take

For high blood pressure:

- The usual starting dose is one 50 mg or 100 mg tablet once a day for one week.
- The dose is then usually increased to 50 mg or 100 mg 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 starting dose is one 50 mg or 100 mg taken two or three times a day.

After myocardial infarction (heart attack):

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

For migraine prevention:

- The usual dose is 100-150 mg taken twice 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 BETALOC

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 use BETALOC tablets

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 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.

If you use too much BETALOC tablets

If you think that you have used too much BETALOC tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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, 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.

5. What should I know while using BETALOC tablets?

Things you should 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 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.

Call your doctor straight away if you:

- become pregnant while taking BETALOC
- have a severe allergic reaction to foods, medicines or insect stings

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 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 should not do

- Do not stop using this medicine suddenly 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 30°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
• 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 Serious side effects are rare.	

Very serious side effects

Very serious side effects	What to do
• 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 side effects are rare.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.** **You may need urgent medical attention or hospitalisation.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BETALOC tablets contains

Active ingredient (main ingredient)	metoprolol tartrate 50 mg or 100 mg

Other ingredients (inactive ingredients)	• lactose monohydrate • microcrystalline cellulose • colloidal anhydrous silica • sodium starch glycollate • povidone • magnesium stearate (E 572)
Potential allergens	• sugars (lactose)

Do not take this medicine if you are allergic to any of these ingredients.

What BETALOC tablets 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 (Aust R 12065).

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 (Aust R 12384).

Who distributes BETALOC tablets

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

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