BETALOC® INJECTION

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 INJECTION?

BETALOC INJECTION contains the active ingredient metoprolol tartrate. BETALOC INJECTION is used to treat irregular heartbeat, also known as arrhythmia, which means that there is a disturbance of the heart's normal rhythm or beat.

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

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

Do not use BETALOC INJECTION if you have ever had an allergic reaction to metoprolol tartrate or any of the ingredients listed at the end of the CMI, 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 INJECTION? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BETALOC INJECTION 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 INJECTION?

- BETALOC INJECTION is given as a slow injection into a vein.
- BETALOC INJECTION must only be given by a doctor or nurse.
- Your doctor will decide what dose and for how long you will receive BETALOC INJECTION. This depends on your condition and other factors, such as your weight.

More information can be found in Section <u>4. How do I use BETALOC INJECTION?</u> in the full CMI.

5. What should I know while using BETALOC INJECTION?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using BETALOC INJECTION. Tell your doctor if you experience any side effects, including those not listed in this leaflet.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how BETALOC INJECTION affects you.
Drinking alcohol	Tell your doctor if you drink alcohol.

For more information, see Section 5. What should I know while using BETALOC INJECTION? 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 may need urgent medical attention or hospitalisation such as 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) and generally feeling unwell.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

BETALOC® INJECTION

Active ingredient(s): metoprolol tartrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using BETALOC INJECTION. 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 INJECTION.

Where to find information in this leaflet:

1. Why am I using BETALOC INJECTION?

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

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

1. Why am I using BETALOC INJECTION?

BETALOC INJECTION contains the active ingredient metoprolol tartrate. BETALOC INJECTION belongs to a group of medicines called beta-blockers.

BETALOC INJECTION is used to treat irregular heartbeat, also known as arrhythmia, which means that there is a disturbance of the heart's normal rhythm or beat.

Arrhythmias may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, or chemical imbalances. Also, after a heart attack there is a chance of developing arrhythmias.

BETALOC INJECTION helps to restore your heart beat to a more normal rate, particularly if it is beating very fast.

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

Warnings

Do not use BETALOC INJECTION if:

• you are allergic to metoprolol tartrate, or any of the ingredients listed at the end of this leaflet.

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.

- always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- have any other 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 disorders causing poor circulation in the arms and legs
- 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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

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

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

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

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

Children and adolescents

• Do not give BETALOC INJECTION to children.

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

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 and BETALOC INJECTION 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 INJECTION or may affect how well it works. You may need to be given different amounts of your medicine, or you may need to be given different medicines. Your doctor will advise you.

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

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 INJECTION.

4. How BETALOC INJECTION is given?

How you are given BETALOC INJECTION

BETALOC INJECTION is given as a slow injection into a vein.

BETALOC INJECTION must only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you will receive BETALOC INJECTION. This depends on your condition and other factors, such as your weight.

To begin treatment, up to 5 mg of BETALOC INJECTION is given at a rate of 1 to 2mg per minute. This dose may be repeated at 5-minute intervals until a satisfactory effect is achieved.

Your blood pressure and heart will be monitored during the treatment.

If you use too much BETALOC INJECTION

The doctor giving you BETALOC INJECTION will be experienced in its use, so it is unlikely that you will be given an overdose.

However, if you are accidentally given an overdose of BETALOC INJECTION you may have nausea, vomiting, convulsions, extreme slowing of the heart beat, lowered blood pressure, possible heart failure and breathing difficulties. In extreme cases, your skin may turn blue, and you may get shock, unconsciousness or coma.

Your doctor has further information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you believe that you have been given too much BETALOC INJECTION, 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.

5. What should I know while using BETALOC INJECTION?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using BETALOC INJECTION.
- Tell your doctor if you experience any side effects, including those not listed in this leaflet.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BETALOC INJECTION affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

BETALOC INJECTION will be stored in the pharmacy or in the ward.

The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Getting rid of any unwanted medicine

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

BETALOC INJECTION should not be used if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

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 e	ects What to c	lo
 where you had swelling or pai headache, tire aches and pair nausea (feelin, weakness, lack stomach upset constipation dry mouth, chasensation difficulty sleep mood changes 	colour or texture the injection in a vein ness, drowsiness , painful joints sick), vomiting of energy diarrhoea or nges in taste ng, nightmares t-term memory concentrate ting, runny or	you of de id

Serious side effects

mild.

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 symptoms of sunburn happening more quickly than before abnormal thinking or hallucinations buzzing or ringing in the ears, deafness irritated eyes or blurred vision sexual problems 	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. You may need urgent medical attention.

• unusual bleeding or bruising

Serious side effects		What to do
•	constant "flu-like" symptoms with tiredness or lack of energy.	
•	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 	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.
 yellowing of the skin or eyes (jaundice), generally feeling unwell. Very serious side effects are rare. 	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 INJECTION contains

Active ingredient (main ingredient)	metoprolol tartrate
Other ingredients	sodium chloride, water for
(inactive	injections
ingredients)	

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

What BETALOC INJECTION looks like

BETALOC INJECTION (1 mg/ mL) is a clear, colourless liquid in glass ampoules of 5 mL, in packs of 5 (Aust R 12063).

Who distributes BETALOC INJECTION

AstraZeneca Pty Ltd ABN 54 009 682 311 66 Talavera Road MACQUARIE PARK NSW 2113 Telephone:- 1800 805 342

This leaflet was prepared in August 2024.

BETALOC[®] is a registered trademark of the AstraZeneca group of companies.

© AstraZeneca, 2024

VV-RIM-04911960 v3.0