

BETALOC® INJECTION

Metoprolol tartrate

Consumer Medicine Information

What is in this leaflet

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

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 your being given BETALOC INJECTION against the benefits they expect it will have for you.

This medicine is likely to be used in emergency situations where you may be unconscious. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given after the medicine has been used.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What BETALOC INJECTION is for

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.

Your doctor will have explained why you are being treated with BETALOC INJECTION and told you what dose you will be given.

Ask your doctor if you have any questions about why BETALOC INJECTION 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 INJECTION is not addictive.

Before you are given BETALOC INJECTION

When you must not be given it

Do not use BETALOC INJECTION if:

- **you have any allergies to metoprolol tartrate, the active ingredient in BETALOC INJECTION, 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.

BETALOC INJECTION should not be used 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 INJECTION to children.

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

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

Before you are given it

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 or 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
- pheochromocytoma, a rare tumour of the adrenal gland
- any blood vessel disorders 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 INJECTION 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 INJECTION 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 the above, tell them before you are given BETALOC INJECTION.

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 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.

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

How BETALOC INJECTION is given

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 5mg 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 are given too much

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

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given BETALOC INJECTION.

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

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.

Ask your doctor to answer any questions you may have.

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

- swelling, burning sensation, changes in skin colour or texture where you had the injection
- swelling or pain in a vein
- headache, tiredness, drowsiness
- aches and pains, painful joints
- nausea (feeling sick), vomiting
- weakness, lack of energy

- stomach upset, diarrhoea or constipation
- 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
- weight gain.

These side effects are usually mild.

Tell your doctor or nurse 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
- 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
- unusual bleeding or bruising
- constant "flu-like" symptoms with tiredness or lack of energy.

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, 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, nurse 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 BETALOC INJECTION

Storage

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

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

Product description

What BETALOC INJECTION looks like

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

Ingredients

BETALOC INJECTION does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Each BETALOC INJECTION contains metoprolol tartrate as the active ingredient;

plus

- sodium chloride
- water for injections.

Sponsor

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Australian Registration Number

Betaloc Injection 5mg/5mL - Aust R 12063

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