

Brevibloc[®] Powder for Injection

Contains Esmolol Hydrochloride 2500mg per vial

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Brevibloc Powder for Injection. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Brevibloc Powder for Injection against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Brevibloc Powder for Injection is used for

Brevibloc Powder for Injection is used as a short-term treatment for irregular heartbeat before, during or after surgery. It is also used in emergency situations.

Irregular heartbeat, also known as arrhythmia, means that there is a disturbance of the heart's normal rhythm or beat. Arrhythmia may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, or chemical imbalances. Brevibloc Powder for Injection helps restore the heart's normal rhythm.

Brevibloc Powder for Injection belongs to a group of medicines called beta-blockers.

Ask your doctor if you have any questions about why Brevibloc Powder for Injection has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is not enough information to recommend the use of Brevibloc Powder for Injection in children.

Before you are given Brevibloc Powder for Injection

When you must not be given it

You should not be given Brevibloc Powder for Injection if you have an allergy to:

- any medicine containing esmolol hydrochloride
- any of the ingredients listed at the end of this leaflet
- any other beta-blocker medicines.

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.

You should not be given Brevibloc Powder for Injection if:

- you have a very slow or irregular heart beat
- you have heart disease or certain other heart conditions
- you are taking certain heart medicines, called calcium channel blockers or calcium antagonists, such as verapamil
- you are receiving emergency treatment for shock or severely low blood pressure.

You should not be given Brevibloc Powder for Injection if the final solution after reconstitution and dilution is discoloured, cloudy, turbid, or if particles or a precipitate is present. The final solution is normally a clear, colourless liquid from visible particles.

You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If this medicine is used after the expiry date it may not work as well.

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

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods preservatives or dyes.

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

- low blood pressure
- any other heart problem
- history of severe life threatening allergic reactions
- asthma, wheezing, difficulty breathing or other lung problems
- diabetes
- low sugar levels in the blood
- kidney problems.
- psoriasis

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given Brevibloc Powder for Injection.

Taking other medicines

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

Some medicines and Brevibloc Powder for Injection may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- verapamil, a calcium channel blocker or calcium antagonist which is used to treat high blood pressure and chest pain
- reserpine, a medicine used to treat high blood pressure
- succinylcholine a muscle relaxant used during surgery
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- morphine, a medicine used for pain relief
- medicines commonly used during surgery or in emergency situations such as dopamine, adrenaline, noradrenaline and certain anaesthetics.

These medicines may be affected by Brevibloc Powder for Injection, or may affect how well it works. You may need to be given different amounts of your medicines, or you may need to be given different medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given Brevibloc Powder for Injection.

How Brevibloc Powder for Injection is given

Brevibloc Powder for Injection must only be given by a doctor or nurse.

The powder for injection must be reconstituted and diluted before use. The final solution is given as a slow infusion into a vein.

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

If you are given too much (overdose)

Brevibloc Powder for Injection must only be given by a doctor or nurse so an overdose is not likely to occur.

Symptoms of an overdose may include:

- dizziness, faintness or light-headedness
- chest pain
- drowsiness and loss of consciousness.

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

While you are being given Brevibloc Powder for Injection

Things you must do

If you are about to be started on any new medicines, remind your doctor or pharmacist that you have recently been given Brevibloc Powder for Injection.

Tell any other doctors or dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during the surgery.

If you plan to become pregnant, tell your doctor that you have been given this medicine. Your doctor can discuss with you the risks and benefits involved.

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 Brevibloc Powder for Injection may cause allergic reactions to be worse and more difficult to treat.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

Brevibloc Powder for Injection may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heartbeat. Brevibloc Powder for Injection may make low blood sugar last longer. Your doses of diabetic medicines, including insulin, may need to change.

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

Things to be careful of

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 after you are given Brevibloc Powder for Injection. 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Brevibloc Powder for Injection.

This medicine helps most people with irregular heartbeat, but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following list of side effects you may not experience any of them.

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:

- tiredness, drowsiness, sweating, decreased alertness
- weakness, lack of energy
- shakiness, trembling, muscle stiffness
- headache
- aches and pains
- changes in mood such as anxiety, agitation, depression
- confusion
- stomach upset, diarrhoea or constipation
- loss of appetite, feeling sick, vomiting
- dry mouth, change in taste sensation
- runny or blocked nose
- flushed or pale skin.

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- dizziness or light-headedness (sometimes with fainting), especially on standing up
- skin reactions at the injection site (*e.g.*, swelling, redness or burning sensation, change in skin colour or hardness)
- visual disturbances (*e.g.*, blurred vision)
- difficulty in speaking
- fever and chills.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- abnormal thinking or hallucinations (seeing, feeling or hearing things that are not there)
- shortness of breath, sometimes with tiredness, weakness and reduced ability to exercise, swelling of the feet or legs due to fluid build up
- chest pain, changes in heart rate (fast, slow or irregular), palpitations
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, which may be signs of a serious allergic reaction

- chest tightness, wheezing, rattly breathing
- a change in the amount or frequency of urine passed
- tingling or pins and needles in the hands and feet
- coldness, burning or numbness or pain and the arms and/or legs
- seizures, fits or convulsions.

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

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Brevibloc Powder for Injection

Storage

Brevibloc Powder for Injection will be stored in the pharmacy or on the ward of a hospital. The powder for injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Store in the original packaging.

Brevibloc Powder for Injection will be reconstituted and diluted for use on you. It will be used only once and then it will be discarded. It will never be used for more than one person.

Product description

What it looks like

Brevibloc Powder for Injection is a white to almost white powder in a clear glass vial with a plastic top.

Brevibloc Powder for Injection is available in a 50mL vial.

Ingredients

Brevibloc Powder for Injection contains esmolol hydrochloride 2500mg with no other excipients.

Supplier

Brevibloc Powder for Injection is supplied in Australia by:

Phebra Pty Ltd
19 Orion Road
Lane Cove West, NSW 2066
Australia

Brevibloc 2500mg powder for injection.50mL vial.
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