Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dobutrex. It does not contain all the available information and does not take the place of talking with your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Dobutrex is used for

This medicine contains dobutamine (as dobutamine hydrochloride) as the active ingredient. It belongs to a group of medicines called catecholamines, which are a synthetic version of a naturally occurring chemical, adrenaline.

Dobutrex is used to treat patients who need shortterm treatment of heart failure following a heart attack or heart surgery.

It works by strengthening the pumping action of the heart, increasing the amount of blood flowing to the body and by expanding both veins and arteries, so the heart can more easily propel the blood. It helps your heart work more effectively.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

There is not enough safety and efficacy information available to recommend the use of Dobutrex in children.

Before you are given it

When you must not be given it

You must not be given Dobutrex if you have ever had an allergic reaction to:

- any medicine containing dobutamine hydrochloride
- 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.

You must not be given this medicine if you have a condition called idiopathic hypertrophic sub aortic stenosis (i.e. a narrowing of the artery coming from your heart).

Before you are given it

Tell your doctor if you are allergic to any other medicines, or any foods, preservative or dyes.

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

- hypokalaemia (i.e. low potassium levels)
- high blood pressure
- fast or irregular heart beat

· other heart problems.

Tell your doctor if you are pregnant or intend to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved

If you have not told your doctor about any of the above, tell them before you start being given Dobutrex.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Dobutrex. These include:

- · some general anaesthetics, such as halothane
- · nitroprusside and nitroglycerin
- other adrenergic agents (adrenaline-like agents).

These medicines may be affected by Dobutrex or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist have more information on medicines to be careful with or avoid while having this medicine.

How it is given

Dobutrex is a sterile powder which is dissolved and diluted with suitable sterile fluids. It is given as a slow injection into a vein, known as a continuous infusion or a 'drip'.

Your doctor or nurse will prepare the infusion of Dobutrex for you.

How much to be given

Your doctor will decide the dose of Dobutrex you will be given and will adjust the flow rate and duration accordingly.

If you are given too much (overdose)

As you will be given Dobutrex under the supervision of your doctor, it is unlikely that you will receive too much.

However, if you experience any side effects after being given Dobutrex, immediately tell your doctor or nurse or call the Poisons Information Centre (telephone 13 11 26) for advice.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose may include loss of appetite, nausea, vomiting, tremor, anxiety, fast or irregular heartbeats, headache, shortness of breath and chest pain.

While you are using it

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are having Dobutrex, especially if you are being started on any new medicines.

Tell your surgeon or anaesthetist if you are having Dobutrex if you are about to undergo surgery or an operation.

It may affect other medications used during surgery.

If you are about to have any blood tests tell your doctor that you are having Dobutrex. It may interfere with the results of some tests.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Dobutrex.

This medicine helps most people with heart failure 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 attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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

- nausea
- fever
- headache.

These side effects are usually mild.

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

- pain where the needle went into your vein or pain along the vein following injection
- fast or irregular heartbeat
- non-specific chest pain
- difficulty in breathing, wheezing or coughing
- redness or itching of the skin
- bleeding or bruising more easily than normal
- feeling faint.

The above list includes serious side effects which may require medical attention. These side effects are rare.

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

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

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

Product Description

What it looks like

Dobutrex 250 mg powder for injection is a white to off-white powder in a glass vial with a rubber stopper. The powder is dissolved in a suitable sterile solution before it is used.

Available in packs of 1 vial.

Storage

Dobutrex 250 mg powder for injection will be stored in the hospital pharmacy or on the ward. It should be kept in a cool dry place where the temperature stays below 25°C.

Ingredients

Active ingredient:

Each vial contains 250 mg dobutamine (as dobutamine hydrochloride).

Inactive ingredients:

- mannitol
- water for injections
- hydrochloric acid
- sodium hydroxide.

Dobutrex 250 mg powder for injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos St St Leonards NSW 2065

Australia

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