DBL[™] Dobutamine Hydrochloride Injection

Dobutamine Hydrochloride (do-BEWT-a-meen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Dobutamine Hydrochloride Injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DBL Dobutamine Hydrochloride Injection 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 in a safe place. You may need to read it again.

What DBL Dobutamine Hydrochloride Injection is used for

DBL Dobutamine Hydrochloride Injection is used in patients who require short-term treatment of heart failure following a heart attack or heart surgery.

DBL Dobutamine Hydrochloride Injection acts directly on the heart muscle to increase the force of each contraction.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why DBL Dobutamine Hydrochloride

Injection has been prescribed for you.

There is no evidence that DBL Dobutamine Hydrochloride Injection is addictive.

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

Before you are given DBL Dobutamine Hydrochloride Injection

When you must not be given it

You must not be given DBL Dobutamine Hydrochloride Injection if you have an allergy to dobutamine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to DBL Dobutamine Hydrochloride Injection 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 DBL Dobutamine Hydrochloride Injection if you have any of the following medical conditions:

 a heart condition called idiopathic hypertrophic sub aortic stenosis (a narrowing of an artery coming from the heart).

DBL Dobutamine Injection is not recommended in children as the

safety and effectiveness of dobutamine in children have not been established.

If you are not sure whether you should be given DBL Dobutamine Hydrochloride Injection, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

DBL Dobutamine Hydrochloride Injection is not recommended for use during pregnancy. If there is a need to consider dobutamine during pregnancy, your doctor will discuss with you the benefits and risks of being given it.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

You should not breast-feed while being given DBL Dobutamine Hydrochloride Injection.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start

being given DBL Dobutamine Hydrochloride Injection.

Taking other medicines

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

Some medicines and dobutamine may interfere with each other. These include:

- some general anaesthetics, such as halothane
- beta-blockers, a type of medication used for heart and blood pressure problems
- entacapone, a medicine used for Parkinson's disease
- glyceryl trinitrate, a medicine used for angina.

These medicines may be affected by DBL Dobutamine Hydrochloride Injection, or may affect how well it works. You may need different amounts of your medicine, or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given DBL Dobutamine Hydrochloride Injection.

How DBL Dobutamine Hydrochloride Injection is given

How much is given

Your doctor will decide what dose of dobutamine you will receive. This depends on your condition and other factors, such as your weight.

How it is given

DBL Dobutamine Hydrochloride Injection is given as a slow injection into a vein (via a 'drip'). It must only be given by a doctor or nurse.

If you take too much (overdose)

As DBL Dobutamine

Hydrochloride Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given DBL Dobutamine Hydrochloride Injection, immediately tell your doctor or nurse or call the Poisons Information Centre (telephone 13 11 26 in Australia for advice.

Symptoms of a dobutamine overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Dobutamine Hydrochloride Injection.

It 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 treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- nausea and vomiting
- headache
- fever

• pain or tenderness at the injection site.

Tell your doctor, nurse or pharmacist immediately if you notice any of the following:

- chest pain (such as angina pain)
- shortness of breath
- difficult breathing
- fast or irregular heart beat
- signs of an allergic reaction, such as those listed at the start of the leaflet.
- tremors or shaking
- feeling anxious or nervous
- skin rash, itching or hives
- itchy scalp (pruritus).

These may be serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients.

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

After you have been given DBL Dobutamine Hydrochloride Injection

Storage

DBL Dobutamine Hydrochloride 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 25C.

Product description

What it looks like

DBL Dobutamine Hydrochloride Injection is a clear, colourless or slightly yellow solution.

Ingredients

Active ingredients:

• dobutamine hydrochloride

Other ingredients:

- sodium metabisulfite
- water for injection

DBL Dobutamine Hydrochloride Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL Dobutamine Hydrochloride Injection is supplied by:

Pfizer Australia Pty Ltd Sydney NSW Toll Free Number: 1800 675 229 www.pfizer.com.au

Dobutamine Hydrochloride Injection is supplied as:

 250 mg /20 mL vials. AUST R 46451

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