### DBL<sup>™</sup> Dobutamine Hydrochloride Injection

#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 being treated with DBL Dobutamine Hydrochloride Injection?

DBL Dobutamine Hydrochloride Injection contains the active ingredient dobutamine hydrochloride. DBL Dobutamine Hydrochloride Injection is used in patients who require short-term treatment of heart failure following a heart attack or heart surgery.

For more information, see Section <u>1. Why am I being</u> <u>treated with DBL Dobutamine Hydrochloride Injection?</u> in the full CMI.

# 2. What should I know before treatment with DBL Dobutamine Hydrochloride Injection?

Do not use if you have ever had an allergic reaction to dobutamine hydrochloride, sodium metabisulfite or any of the other ingredients listed at the end of the CMI.

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 <u>2. What should I know</u> <u>before treatment with DBL Dobutamine Hydrochloride</u> <u>Injection?</u> in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with DBL Dobutamine Hydrochloride Injection and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

### 4. How is DBL Dobutamine Hydrochloride Injection given?

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

DBL Dobutamine Hydrochloride Injection is given to you by a doctor or nurse as a slow injection into a vein (via a 'drip').

More instructions can be found in Section <u>4. How is DBL</u> <u>Dobutamine Hydrochloride Injection given?</u> in the full CMI.

### 5. What should I know during treatment with DBL Dobutamine Hydrochloride Injection?

Things you should do	<ul> <li>Remind any doctor, nurse, pharmacist or dentist you visit that you were or are being treated with DBL Dobutamine Hydrochloride Injection.</li> </ul>
Driving or using machines	<ul> <li>Be careful before you drive or use any machines or tools until you know how DBL Dobutamine Hydrochloride Injection affects you.</li> </ul>

For more information, see Section <u>5. What should I know</u> <u>during treatment with DBL Dobutamine Hydrochloride</u> <u>Injection?</u> in the full CMI.

### 6. Are there any side effects?

Side effects include: nausea and vomiting, and headache. Serious side effects include: pain or tenderness at the injection site, allergic reaction symptoms (which 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), fast or irregular heart beat, chest pain (such as angina pain), shortness of breath, tremors or shaking, and feeling anxious or nervous.

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

### DBL<sup>™</sup> Dobutamine Hydrochloride Injection

Active ingredient(s): Dobutamine Hydrochloride (do-BEWT-a-meen)

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using DBL Dobutamine Hydrochloride 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 being treated with DBL Dobutamine Hydrochloride Injection.

#### Where to find information in this leaflet:

1. Why am I being treated with DBL Dobutamine Hydrochloride Injection?

2. What should I know before treatment with DBL Dobutamine Hydrochloride Injection?

3. What if I am taking other medicines?

4. How is DBL Dobutamine Hydrochloride Injection given?

5. What should I know during treatment with DBL Dobutamine Hydrochloride Injection?

6. Are there any side effects?

7. Product details

### 1. Why am I being treated with DBL Dobutamine Hydrochloride Injection?

### DBL Dobutamine Hydrochloride Injection contains the active ingredient dobutamine hydrochloride.

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.

# 2. What should I know before treatment with DBL Dobutamine Hydrochloride Injection?

### Warnings

### You must not be given DBL Dobutamine Hydrochloride Injection if:

- 1. you are allergic to dobutamine hydrochloride, sodium metabisulfite or any of the other 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.

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

2. you have a heart condition called idiopathic hypertrophic subaortic stenosis (a narrowing of an artery coming from the heart).

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

### Check with your doctor if you:

- have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
  - high blood pressure
  - fast or irregular heart beat
  - other heart problems
  - low potassium levels (hypokalaemia)
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, tell them before you start being treated with DBL Dobutamine Hydrochloride Injection.

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.

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.

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

You should not breastfeed while being given DBL Dobutamine Hydrochloride Injection.

### Use in Children

DBL Dobutamine Hydrochloride Injection is not recommended in children as the safety and effectiveness of dobutamine in children have 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 may interfere with DBL Dobutamine Hydrochloride Injection and affect how it works.

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 treated with DBL Dobutamine Hydrochloride 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 DBL Dobutamine Hydrochloride Injection.

### 4. How is DBL Dobutamine Hydrochloride Injection 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 is it 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 are given too much DBL Dobutamine Hydrochloride Injection

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.

If you think that you have been given too much DBL Dobutamine Hydrochloride Injection, you may need urgent medical attention.

#### You should immediately:

- contact your doctor, or
- phone the Poisons Information Centre (by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of a dobutamine overdose include the side effects listed below in Section 6. Are there any side effects? but are usually of a more severe nature.

# 5. What should I know during treatment with DBL Dobutamine Hydrochloride Injection?

### Things you should do

Remind any doctor, nurse, pharmacist or dentist you visit that you were or are being treated with DBL Dobutamine Hydrochloride Injection.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Dobutamine Hydrochloride Injection affects you.

### **Drinking alcohol**

Tell your doctor if you drink alcohol.

### 6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Side effects

Side effects	What to do
<ul> <li>General</li> <li>nausea and vomiting</li> <li>headache</li> <li>fever</li> <li>Administration site conditions</li> </ul>	Speak to your doctor, nurse or pharmacist if you have any of these side effects and they worry you.
<ul> <li>pain or tenderness at the injection site</li> </ul>	

### Serious side effects

Serious side effects	What to do
Allergic reaction symptoms	Call your doctor, nurse or pharmacist straight away, or go straight
<ul> <li>This includes:</li> <li>shortness of breath, wheezing or difficulty breathing</li> </ul>	to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul> <li>swelling of the face, lips, tongue or other parts of the body</li> </ul>	
<ul> <li>rash, itching or hives on the skin.</li> </ul>	
<ul> <li>itchy scalp (pruritus)</li> </ul>	
Heart related	
<ul> <li>fast or irregular heart beat</li> </ul>	
<ul> <li>chest pain (such as angina pain)</li> </ul>	
Respiratory related	
<ul> <li>shortness of breath</li> </ul>	
Nervous system related	
<ul> <li>tremors or shaking</li> </ul>	
Changes in behaviour, thinking or mood	
<ul> <li>feeling anxious or nervous</li> </ul>	

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.

### **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 <u>www.tga.gov.au/reporting-problems</u>. 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 DBL Dobutamine Hydrochloride Injection contains

Active ingredient (main ingredient)	dobutamine hydrochloride
Other ingredients	sodium metabisulfite
(inactive ingredients)	water for injections

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

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

## What DBL Dobutamine Hydrochloride Injection looks like

DBL Dobutamine Hydrochloride Injection is a clear, colourless or slightly yellow solution. (Aust R 46451).

DBL Dobutamine Hydrochloride Injection is supplied as 250 mg/20 mL vials.

### How is DBL Dobutamine Hydrochloride Injection stored

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 25°C.

## Who distributes DBL Dobutamine Hydrochloride Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.au

This leaflet was prepared in August 2022.