DBL™ Ephedrine Sulfate 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 Ephedrine Sulfate Injection?

DBL Ephedrine Sulfate Injection contains the active ingredient ephedrine sulfate. DBL Ephedrine Sulfate is used to treat some forms of shock, low blood pressure that occurs when a local anaesthetic is given around the spinal cord, and in the treatment of asthma and spasm of the airways.

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

2. What should I know before treatment with DBL Ephedrine Sulfate Injection?

DBL Ephedrine Sulfate Injection should not be used if you have ever had an allergic reaction to ephedrine sulfate; have closed angle glaucoma, pheochromocytoma, certain problems with the heart or heart rate, an anxiety disorder with obsessive behaviours; have taken monoamine oxidase inhibitors within the last 14 days.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or breastfeeding.

For more information, see Section <u>2. What should I know</u> <u>before treatment with DBL Ephedrine Sulfate Injection?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Ephedrine Sulfate Injection and affect how it works. Examples include medicines used to treat high blood pressure, manage depression, make urine less acidic, treat heart failure, or treat asthma and other related lung problems.

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 Ephedrine Sulfate Injection given?

Your doctor will give you DBL Ephedrine Sulfate Injection by injection into a muscle, vein, or under the skin and decide how much you will be given and for how long.

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

5. What should I know during treatment with DBL Ephedrine Sulfate Injection?

Things you should do	 Remind any doctor or nurse that you have been given DBL Ephedrine Sulfate Injection.
Driving or using machines	 Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given DBL Ephedrine Sulfate Injection.
Drinking alcohol	 No information available.
Looking after your medicine	 The hospital will appropriately store and dispose of this medicine.

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

6. Are there any side effects?

Side effects include sudden life-threatening allergic reactions (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); difficult or painful urination/weeing; feeling sick; an upset stomach or vomiting; a feeling of pain or pressure in the chest; difficulty breathing or shortness of breath; a fast, slow or irregular heartbeat; dizziness; lightheadedness; pale skin; fever or sweating; headache; a dry nose, mouth and throat; difficulty sleeping; mood changes; irritability; nervousness; restlessness; abnormal thoughts; confusion.

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™ Ephedrine Sulfate Injection

Active ingredient(s): ephedrine sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Ephedrine Sulfate Injection. You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about treatment with DBL Ephedrine Sulfate Injection.

Where to find information in this leaflet:

1. Why am I being treated with DBL Ephedrine Sulfate Injection?

2. What should I know before treatment with DBL Ephedrine Sulfate Injection?

- 3. What if I am taking other medicines?
- 4. How is DBL Ephedrine Sulfate Injection given?
- 5. What should I know during treatment with DBL Ephedrine Sulfate Injection?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with DBL Ephedrine Sulfate Injection?

DBL Ephedrine Sulfate Injection contains the active ingredient ephedrine sulfate. DBL Ephedrine Sulfate Injection is a type of medicine called a sympathomimetic agent. You may also hear it referred to as a pressor when used to raise blood pressure. DBL Ephedrine Sulfate Injection works by activating the sympathetic nervous system which leads to relaxation of the muscles in your airway, contraction of blood vessels and stimulation of the heart.

DBL Ephedrine Sulfate Injection is used to treat some forms of shock, low blood pressure that occurs when a local anaesthetic is given around the spinal cord, and in the treatment of asthma and spasm of the airways.

2. What should I know before treatment with DBL Ephedrine Sulfate Injection?

Warnings

DBL Ephedrine Sulfate Injection should not be used if you have:

- an allergy to ephedrine sulfate
- closed angle glaucoma (a buildup of pressure in the eye due to a blockage),

- pheochromocytoma (a rare tumour of the adrenal gland, which sits near the kidneys),
- certain problems with the heart or heart rate,
- taking or have taken monoamine oxidase (MAO) inhibitors within the last 14 days, e.g. phenelzine or tranylcypromine
- an anxiety disorder including obsessive behaviours.

Check with your doctor if you have:

- kidney problems or weakness, tiredness, dizziness and increased thirst,
- too much acid in your blood (metabolic acidosis) causing nausea, vomiting, drowsiness and breathlessness
- lung problems or difficulty breathing
- problems with your heart, including angina
- high blood pressure
- overactive thyroid
- diabetes
- problems urinating/weeing or prostate problems if you are a man.

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.

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

DBL Ephedrine Sulfate Injection has been shown to pass into breast milk. Discuss breastfeeding during this period with your doctor.

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 affect or be affected by DBL Ephedrine Sulfate Injection. These include:

- alpha blockers or beta blockers and other medicines used to treat high blood pressure, e.g. prazosin, propranolol, methyldopa, clonidine
- medicines used to manage depression such as tricyclic antidepressants (TCAs), e.g. amitriptyline, clomipramine, dothiepin, imipramine
- medicines to make urine less acidic, e.g. acetazolamide, dichlorphenamide, sodium bicarbonate, sodium citrate
- medicines used during anaesthesia e.g. inhalation anaesthetics
- medicines used to treat heart failure, e.g. digoxin
- theophylline, used to treat asthma and other related lung problems.

Check with your doctor or nurse if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Ephedrine Sulfate Injection.

4. How is DBL Ephedrine Sulfate Injection given?

How is DBL Ephedrine Sulfate Injection given

 Your doctor will give you DBL Ephedrine Sulfate Injection by injection into a muscle, vein, or under the skin.

How much will be given

 Your doctor will decide how much DBL Ephedrine Sulfate Injection you will be given and how long you will be given it.

If you are given too much DBL Ephedrine Sulfate Injection

As DBL Ephedrine Sulfate Injection doses are carefully worked out and given by a doctor experienced in its use, and you will be monitored carefully, it is extremely unlikely that you will be given too much.

Signs that you may have been given too much include headache, nausea, vomiting, dizziness, lightheadedness, emotional changes, hallucinations, blurred vision, chest pain or problems breathing. Tell your doctor or nurse immediately if you experience these.

5. What should I know during treatment with DBL Ephedrine Sulfate Injection?

Things you should do

Remind any doctor or nurse, that you have been given DBL Ephedrine Sulfate Injection.

Things you should not do

Driving or using machines

Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given DBL Ephedrine Sulfate Injection.

There is no information on the effects of this medicine on a person's ability to drive and use machines.

Drinking alcohol

No information available.

Looking after the medicine

DBL Ephedrine Sulfate Injection will be stored appropriately at the hospital.

Getting rid of any unwanted medicine

The hospital staff will dispose of any leftover DBL Ephedrine Sulfate Injection.

6. Are there any side effects?

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
 pale skin fever or sweating headache dry nose, mouth and	Speak to your doctor or
throat difficulty sleeping mood changes,	nurse if you have any of
irritability, nervousness,	these side effects and
restlessness	they worry you.

Side effects	What to do
 difficult or painful urination/weeing feeling sick, an upset stomach or vomiting a feeling of pain or pressure in the chest difficulty breathing or shortness of breath a fast, slow or irregular heartbeat dizziness, lightheadedness abnormal thoughts or confusion signs of an allergic reaction such as 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. 	Speak to your doctor or nurse as soon as possible if you notice any of these side effects.

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 sideeffects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/safety/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 Ephedrine Sulfate Injection contains

Active ingredient	Ephedrine Sulfate
(main ingredient)	
Other ingredients	Sodium Chloride
(inactive ingredients)	Water for injections

This medicine should not be used if you are allergic to any of these ingredients.

DBL Ephedrine Sulfate Injection does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

What DBL Ephedrine Sulfate Injection looks like

DBL Ephedrine Sulfate Injection is a clear colourless solution (AUST R 16325).

Who distributes DBL Ephedrine Sulfate Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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