DBL™ STERILE DOPAMINE CONCENTRATE

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 given DBL STERILE DOPAMINE CONCENTRATE?

DBL STERILE DOPAMINE CONCENTRATE contains the active ingredient dopamine hydrochloride. Dopamine may be used to increase low blood pressure in people who have experienced a heart attack, a severe infection, lost blood during an accident, kidney failure or problems after surgery. Dopamine may be used to help the heart pump better in some people with congestive heart failure. Your doctor may have prescribed DBL STERILE DOPAMINE CONCENTRATE for another reason.

For more information, see Section <u>1. Why am I being given DBL STERILE DOPAMINE CONCENTRATE?</u> in the full CML

2. What should I know before I am given DBL STERILE DOPAMINE CONCENTRATE?

Do not use if you have ever had an allergic reaction to dopamine or any of the 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 2. What should I know before I am given DBL STERILE DOPAMINE CONCENTRATE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL STERILE DOPAMINE CONCENTRATE and affect how it works.

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

4. How is DBL STERILE DOPAMINE CONCENTRATE given?

 DBL STERILE DOPAMINE CONCENTRATE is diluted and given slowly as an infusion (a drip) into a vein. It

- must only be given by a doctor, nurse or other trained person.
- Your doctor will decide what dose you will receive.
 This depends on your condition and other factors, such as your weight.

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

5. What should I know while being given DBL STERILE DOPAMINE CONCENTRATE?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are receiving DBL STERILE DOPAMINE CONCENTRATE.
Driving or using machines	 Be careful driving or operating machinery until you know how this medicine affects you. If you are feeling dizzy or drowsy do not drive, operate machinery, or do anything else that could be dangerous.

For more information, see Section <u>5. What should I know while being given DBL STERILE DOPAMINE CONCENTRATE?</u> in the full CMI.

6. Are there any side effects?

Common side effects of this medicine may include: dizziness, nausea, vomiting, headache and anxiety.

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™ STERILE DOPAMINE CONCENTRATE

Active ingredient(s): Dopamine (DO-pa-meen)

hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL STERILE DOPAMINE CONCENTRATE. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL STERILE DOPAMINE CONCENTRATE.

Where to find information in this leaflet:

- 1. Why am I being given DBL STERILE DOPAMINE CONCENTRATE?
- 2. What should I know before I am given DBL STERILE DOPAMINE CONCENTRATE?
- 3. What if I am taking other medicines?
- 4. How is DBL STERILE DOPAMINE CONCENTRATE given?
- 5. What should I know while being given DBL STERILE DOPAMINE CONCENTRATE?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being given DBL STERILE DOPAMINE CONCENTRATE?

DBL STERILE DOPAMINE CONCENTRATE contains the active ingredient dopamine hydrochloride.

Dopamine acts in different ways, depending on the dose given. At low doses, dopamine increases blood flow to the kidneys. At higher doses, it increases the blood flow to the muscles and can increase the heart's pumping efficiency.

Dopamine may be used to increase low blood pressure in people who have:

- experienced a heart attack
- a severe infection
- lost blood during an accident
- kidney failure
- problems after surgery.

Dopamine may be used to help the heart pump better in some people with congestive heart failure.

Your doctor may have prescribed DBL STERILE DOPAMINE CONCENTRATE for another reason.

Ask your doctor if you have any questions about why DBL STERILE DOPAMINE CONCENTRATE has been prescribed for you.

There is no evidence that dopamine is addictive.

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

2. What should I know before I am given DBL STERILE DOPAMINE CONCENTRATE?

Warnings

You should not be given DBL STERILE DOPAMINE CONCENTRATE if:

- you are allergic to dopamine hydrochloride, or any of the ingredients listed at the end of this leaflet
- you have an adrenal gland tumour (phaeochromocytoma)
- you have a fast or irregular heartbeat (arrhythmia, ventricular fibrillation)
- you have an overactive thyroid gland (hyperthyroidism)
- you are being given certain anaesthetics at the same time
- you are currently using ergotamine, a medicine used to treat migraines.

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

- hardening of the blood vessels
- Raynaud's disease, where the fingers become white and very painful when cold
- diabetes

- frostbite
- high blood pressure
- liver disease
- kidney disease.

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</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

If it is necessary for you to be given dopamine, your doctor will discuss the possible risks and benefits of using it during pregnancy and breastfeeding.

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 STERILE DOPAMINE CONCENTRATE and affect how it works.

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- some anaesthetic agents
- ergotamine, methysergide and dihydroergotamine (medicines used to prevent or treat migraines)
- some heart and blood pressure tablets, including digoxin, prazosin, beta-blockers such as propranolol and metoprolol, calcium channel blockers and glyceryl trinitrate
- antidepressants (MAO inhibitors, tricyclic antidepressants)
- haloperidol or droperidol (medicines used to treat some mental illnesses)
- medicines used to control seizures (fits), such as phenytoin.

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

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 STERILE DOPAMINE CONCENTRATE.

4. How is DBL STERILE DOPAMINE CONCENTRATE given?

How much is given

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

How it is given

- DBL STERILE DOPAMINE CONCENTRATE is diluted and given slowly as an infusion (a drip) into a vein.
- This medicine should only be given by a doctor, nurse or other trained person.

If too much DBL STERILE DOPAMINE CONCENTRATE is given

Since DBL STERILE DOPAMINE CONCENTRATE is given in a hospital or clinic under the supervision of a doctor, it is very unlikely that you will be given too much of the medicine. Your doctor or nurse will be monitoring your progress and checking the medicine that you are given.

If you think that you have been given too much DBL STERILE DOPAMINE CONCENTRATE, you may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in Section <u>6</u>. Are there any side effects? but are usually of a more severe nature.

5. What should I know while being given DBL STERILE DOPAMINE CONCENTRATE?

Things you should do

Keep all your doctor's appointments so that your progress can be checked.

Remind any doctor, dentist or pharmacist you visit that you have been given DBL STERILE DOPAMINE CONCENTRATE.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL STERILE DOPAMINE CONCENTRATE affects you.

DBL STERILE DOPAMINE CONCENTRATE may cause dizziness in some people.

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
dizzinessnauseavomitingheadacheanxiety	Speak to your doctor if you have any of these side effects and they worry you.
 cold or tingling feet which may indicate problems with blood circulation chest pain irregular or rapid heartbeat difficulty breathing 	Call your doctor straight away if you notice any of these serious 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 side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 STERILE DOPAMINE CONCENTRATE contains

Active ingredient	dopamine hydrochloride
(main ingredient)	
Other ingredients	water for injection
(inactive ingredients)	sodium metabisulfite
Potential allergens	sulfites

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

DBL STERILE DOPAMINE CONCENTRATE does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL STERILE DOPAMINE CONCENTRATE looks like

DBL STERILE DOPAMINE CONCENTRATE is a sterile, clear colourless to pale yellow liquid in a glass ampoule.

Each 5 mL ampoule contains 200 milligrams of dopamine hydrochloride. It is available in packs of 5 ampoules.

Australian Registration Number

DBL STERILE DOPAMINE CONCENTRATE 200mg/5mL injection ampoule - AUST R 16378.

Who distributes DBL STERILE DOPAMINE CONCENTRATE

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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