

DBL™ Sterile Cardioplegia Concentrate

Magnesium chloride hexahydrate, Potassium chloride, Procaine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Sterile Cardioplegia Concentrate. 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™ Sterile Cardioplegia Concentrate 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.

You may need to read it again.

What DBL™ Sterile Cardioplegia Concentrate is used for

This medicine is used in open-heart surgery. This medicine contains magnesium and potassium which stop the heart beating and minimise the energy requirements of the heart during surgery. It also contains procaine which protects the heart muscle and helps stop the heart beating during the surgery. Procaine also helps prevent disturbances in heart rhythm straight after the surgery.

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 not addictive.

Before you are given DBL™ Sterile Cardioplegia Concentrate

When you must not be given it

You must not be given DBL™ Sterile Cardioplegia Concentrate if you have an allergy to:

- procaine or other similar local anaesthetics
- para-aminobenzoic acid or its derivatives (used as preservatives and in sunscreens)

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 DBL™ Sterile Cardioplegia Concentrate if you

- have myasthenia gravis, a disease with severe weakness of the muscles
- have been told you have a heartbeat conduction defect
- are taking medicines called anticholinesterases such as pyridostigmine
- are taking medicines from a group of antibiotics, known as sulfonamides

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have ever had any other medical conditions, including:

- liver disease
- kidney disease
- an overactive thyroid gland (hyperthyroidism)
- if you or anyone in your family has had a dangerously high body temperature brought on by general anaesthesia

Tell your doctor if you are pregnant or plan 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 him/her before you are given Sterile Cardioplegia Concentrate.

Taking other medicines

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

Some medicines and DBL™ Sterile Cardioplegia Concentrate may interfere with each other. These include:

- medicines which are used to treat myasthenia gravis, such as pyridostigmine
- acetazolamide, a medicine used to treat glaucoma, fluid retention and certain rare types of epilepsy (fits)
- medicines used to help you sleep or to treat anxiety or depression
- strong pain relievers
- diuretics (fluid tablets) such as triamterene, spironolactone and amiloride
- angiotensin converting enzyme (ACE) inhibitors, medicines for high blood pressure and some other heart conditions
- medicines containing potassium
- cyclosporin, a medicine used to reduce the activity of the body's immune system
- a group of antibiotics for treating infections, known as sulfonamides
- hyaluronidase, used for bruising and preventing skin reactions to chemotherapy
- neuromuscular blocking agents, medicines used to relax muscles.

Although it is unlikely, these medicines may be affected by DBL™ Sterile Cardioplegia Concentrate 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 and pharmacist have more information on medicines to be careful with or to avoid while being given DBL™ Sterile Cardioplegia Concentrate.

How DBL™ Sterile Cardioplegia Concentrate is given

How much is given

Your doctor will decide how much DBL™ Sterile Cardioplegia Concentrate you will receive and how long you will receive it for. This depends on the type of open-heart

surgery you are receiving and other factors such as your weight and height.

How it is given

DBL™ Sterile Cardioplegia Concentrate is diluted with Ringer's Injection before use and infused through the heart.

It must only be given by a person trained in open-heart surgery.

If you receive too much (overdose)

As DBL™ Sterile Cardioplegia Concentrate is given to you in hospital under the supervision of your doctor, it is unlikely that you will receive too much. Your doctor has information on how to recognise and treat an overdose.

Ask your doctor if you have any concerns.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well after you have been given DBL™ Sterile Cardioplegia Concentrate.

This medicine helps most people undergoing open-heart surgery, but it may have unwanted side effects in some 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 side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Tell your doctor or nurse immediately if you notice any of the following after the surgery:

- nausea
- muscle twitching, tremors or convulsions (fits)
- irregular or slow heartbeat.

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

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

Ask your doctor to answer any questions you may have about possible side effects.

Your doctor will monitor you closely during the surgery for any side effects.

After you are given DBL™ Sterile Cardioplegia Concentrate

Storage

DBL™ Sterile Cardioplegia Concentrate will generally be stored in the pharmacy or on the ward. It is kept in a cool, dry place, where the temperature stays below 25°C.

Product Description

What it looks like

DBL™ Sterile Cardioplegia Concentrate is a clear, colourless solution supplied in glass ampoules

Ingredients

Each mL of DBL™ Sterile Cardioplegia Concentrate contains:

- magnesium chloride hexahydrate 162.5 mg,
- potassium chloride 59.5 mg

- and procaine hydrochloride 13.64 mg as the active ingredients.

This medicine also contains:

- water for injection.

DBL™ Sterile Cardioplegia Concentrate does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

DBL™ Sterile Cardioplegia Concentrate is supplied by:

Australian Sponsor:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number : 1800 675 229

www.pfizer.com.au

DBL™ Sterile Cardioplegia Concentrate is available in the following presentation:

- 20mL ampoules x 5
AUST R 16365

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