

DBL™ Cisatracurium Injection Concentrate

Cisatracurium besylate (sis-at-rah-CURE-e-um BESS-ee-late)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Cisatracurium Injection Concentrate (cisatracurium besylate).

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 this medicine 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 with the medicine. You may need to read it again.

What DBL™ Cisatracurium Injection Concentrate is used for

This medicine is used to relax the body's muscles during surgery or other medical procedures.

The medicine contains cisatracurium besylate, which belongs to a family of medicines called neuromuscular blockers.

The medicine works by blocking the effects of one of the body's chemical messengers called acetylcholine. Acetylcholine is involved in muscle contraction.

By relaxing your body's muscles cisatracurium besylate makes it easier for you to be kept asleep (under anaesthesia) or sedation.

Cisatracurium besylate is only used in conjunction with an anaesthetic, so you will be asleep during the procedure.

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.

It is only available with a doctor's prescription.

Before you are given DBL™ Cisatracurium Injection Concentrate

When you must not be given it

Do not have the medicine if you have an allergy to:

- any medicine containing cisatracurium besylate or atracurium
- any of the ingredients listed at the end of this leaflet.

Some of the 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.

Do not take cisatracurium besylate if the packaging is torn or shows signs of tampering.

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

Before you start to take it

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

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

- you are allergic to any other muscle relaxants
- you suffer from myasthenia gravis, or any other form of neuromuscular disease
- you, or a relative have had previous difficulties with anaesthetics
- severe acid-base and/or serum electrolyte abnormalities

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 them before you start using the medicine.

Taking other medicines

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

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

- antibiotics
- anti-arrhythmics, which are used to control irregular heart or rapid heart beat
- diuretics, used to increase your volume of urine
- magnesium or lithium salts
- phenytoin or carbamazepine (for fits)

These medicines may be affected by cisatracurium besylate or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines

Talk to your doctor if you are not sure whether you should be given this medicine.

How DBL™ Cisatracurium Injection Concentrate is given

How much is given

Your doctor will decide what dose of cisatracurium besylate you will receive and how long you will receive it for. This depends on your condition and other factors, such as body weight and the duration of the procedure.

How it is given

DBL™ Cisatracurium Injection Concentrate is given by injection into your vein. This medicine will be administered by an anaesthetist or other highly trained doctor, usually during surgery or other medical procedures.

If you have any questions about the dose that you will receive ask your doctor.

If you have too much (overdose)

Overdoses of DBL™ Cisatracurium Injection Concentrate lead to prolonged relaxation of the body's muscles. This can be readily treated. This situation is unlikely to occur because it is given to you under the supervision of your doctor, so it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given this medicine, tell your doctor or nurse immediately, or, if you are not in hospital, go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention.

Please contact the Poisons Information Centre in Australia on 131 126 or in New Zealand on 0800 764 766 for advice on overdose management.

While you are being given DBL™ Cisatracurium Injection Concentrate

Things you must do

Tell your doctor or pharmacists if you are taking any other medicines.

Tell any other doctors, dentists, or pharmacists who treat you that you are having this medicine.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are having this medicine.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are using this medicine.

It may affect other medicines used during surgery.

Things you must not do

Do not start to take any other medicine before talking to your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how the medicine affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are given this medicine.

This medicine 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

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

- flushing of the face and upper body
- skin rashes
- slow heart beat
- dizziness or light headedness
- difficulty breathing
- muscle weakness

Tell your doctor immediately if you notice any of the side effects even after you have finished your treatment.

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

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

After using DBL™ Cisatracurium Injection Concentrate

Storage

DBL™ Cisatracurium Injection Concentrate should be stored between 2°C to 8°C. Protect from light. Do not freeze.

DBL™ Cisatracurium Injection Concentrate does not contain any antimicrobial preservative. To reduce microbiological hazard, use as soon as practicable after dilution. If storage is necessary, hold at 2°C to 8°C for not more than 24 hours.

Product description

What it looks like

DBL™ Cisatracurium Injection Concentrate is a colourless to pale yellow or greenish solution.

Ingredients

DBL™ Cisatracurium Injection Concentrate contains:

- 5 mg per 2.5mL or
- 10 mg per 5 mL of cisatracurium (as the besylate salt) as the active ingredient.

It also contains:

- benzenesulphonic acid
- water for injection

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

DBL™ Cisatracurium Injection Concentrate is supplied in Australia by:

Australian Sponsor:

Hospira Pty Ltd
ABN 13 107 058 328
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street
Te Aro
Wellington
New Zealand

DBL™ Cisatracurium Injection Concentrate is available in two strengths:

- 5 mg/2.5 mL x 5 vials AUST R 170579
- 10 mg/5 mL x 5 vials AUST R 170580

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