



Package Leaflet: Information for the user
Cisatracurium 2 mg/ml Solution for Injection/Infusion
Cisatracurium

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cisatracurium is and what it is used for
2. What you need to know before you are given Cisatracurium
3. How Cisatracurium is given
4. Possible side effects
5. How to store Cisatracurium
6. Contents of the pack and other information

1. What Cisatracurium is and what it is used for

Cisatracurium 2 mg/ml Solution for Injection/Infusion contains a medicine called cisatracurium. This belongs to a group of medicines called muscle relaxants.

Cisatracurium is used:

- to relax muscles during operations on adults and children over 1 month of age, including heart surgery;
- to help insert a tube into the windpipe (tracheal intubation), if a person needs help to breathe;
- to relax the muscles of adults in intensive care.

Ask your doctor if you would like more explanation about this medicine.

2. What you need to know before you are given Cisatracurium

You should not be given Cisatracurium

- if you are allergic to cisatracurium, any other muscle relaxant or any of the other ingredients of this medicine (listed in section 6);
- you have reacted badly to an anaesthetic before.

Do not have Cisatracurium if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before you have Cisatracurium.

Warnings and precautions

Talk to your doctor or nurse before you are given Cisatracurium:

- if you have muscle weakness, tiredness or difficulty in coordinating your movements (myasthenia gravis);
- you have a neuromuscular disease, such as a muscle wasting disease, paralysis, motor neurone disease or cerebral palsy;
- if you have a burn which requires medical

treatment;

- you have ever had an allergic reaction to any muscle relaxant which was given as part of an operation.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before you are given Cisatracurium.

Other medicines and Cisatracurium

Tell your doctor if you are using, have recently used or might use any other medicines. This includes any herbal products or medicines bought without a prescription.

In particular tell your doctor if you are using any of the following medicines:

- anaesthetics (used to reduce sensation and pain during surgical procedures);
- antibiotics (used to treat infections);
- medicines for uneven heart beats (antiarrhythmic agents);
- medicines for high blood pressure;
- water tablets (diuretics), such as furosemide;
- medicines for inflammation of the joints, such as chloroquine or D-penicillamine;
- steroids;
- medicines for fits (epilepsy), such as phenytoin or carbamazepine;
- medicines for mental illness, such as lithium or chlorpromazine (which can also be used for sickness);
- medicines containing magnesium;
- drugs for Alzheimer's disease (anticholinesterases e.g. donepezil).

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

Do not breast feed for at least 3 hours after your last dose when the effects of cisatracurium have worn off.

Driving and using machines

If you are only staying in hospital for the day, your doctor will tell you how long to wait before leaving the hospital or driving a car. It can be dangerous to drive too soon after having an operation.

3. How Cisatracurium is given

You will never be expected to give yourself this medicine. It will always be given to you by a person who is qualified to do so.

Cisatracurium can be given:

- as a single injection into your vein (intravenous bolus injection);
- as a continuous infusion into your vein. This is

where the drug is slowly given to you over a long period of time.

Your doctor will decide the way you are given the drug and the dose you will receive. It will depend on:

- your body weight;
- the amount and duration of muscle relaxation required;
- your expected response to the medicine.

Children less than 1 month old should not have this medicine.

If you receive more Cisatracurium than you should

This medicine will always be given under carefully controlled conditions. However, if you think that you have been given more than you should tell your doctor or nurse immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

Allergic reactions (affects less than 1 in 10,000 people)

If you have an allergic reaction, tell your doctor or nurse **immediately**. The signs may include:

- sudden wheeziness, chest pain or chest tightness;
- swelling of your eyelids, face, lips, mouth or tongue;
- a lumpy skin rash or hives anywhere on your body;
- a collapse and shock.

Talk to your doctor or nurse if you notice any of the following:

Common (affects less than 1 in 10 people)

- decrease in heart rate;
- decrease in blood pressure.

Uncommon (affects less than 1 in 100 people)

- a rash or redness of your skin;
- wheezing or coughing.

Very rare (affects less than 1 in 10,000 people)

- weak or aching muscles.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cisatracurium

Keep this medicine out of the sight and reach of children.

Store and transport refrigerated (2°C – 8°C). Do not freeze.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the ampoule label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cisatracurium contains

– The active substance is cisatracurium (as besilate). Each ml of solution contains 2 mg of cisatracurium (as cisatracurium besilate).

Each 2.5 ml ampoule contains 5 mg of cisatracurium.

Each 5 ml ampoule contains 10 mg of cisatracurium.

Each 10 ml ampoule contains 20 mg of cisatracurium.

– The other ingredients are benzenesulfonic acid (for pH adjustment), water for injections.

What Cisatracurium looks like and contents of the pack

Clear, colourless or yellowish solution, free from visible particles.

2.5 ml, 5 ml or 10 ml of solution filled in colourless glass ampoules.

Ampoules are marked with a specific colour ring code for each volume.

Five ampoules are placed into a PVC liner. Liner is placed into a carton.

Not all pack sizes may be marketed.

Marketing authorisation holder

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internal code
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manufacturer
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The following information is intended for healthcare professionals only:

Incompatibilities

Degradation of cisatracurium besilate has been demonstrated to occur more rapidly in lactated Ringer's Injection and 5% Dextrose and lactated Ringer's Injection than in the infusion fluids listed under section 6.6. Therefore it is recommended that lactated Ringer's Injection and 5% Dextrose and lactated Ringer's Injection are not used as the diluent in preparing solutions of Cisatracurium for infusion.

Since cisatracurium is stable only in acidic solutions it should not be mixed in the same syringe or administered simultaneously through the same needle with alkaline solutions (e.g. sodium thiopentone).

Cisatracurium is not compatible with ketorolac trometamol or propofol injectable emulsion.

Instructions for use, disposal and other handling

For single use only.

The medicinal product should be used immediately after opening the ampoule.

The medicinal product should be visually inspected prior to use. The medicine should not be used if there are any visible signs of deterioration (e.g. particles).

Diluted Cisatracurium solution is physically and chemically stable for 24 hours at 5°C and 25°C at concentrations between 0.1 mg/ml and 1.5 mg/ml in the following infusion fluids when in contact with polypropylene or polycarbonate syringes, polyethylene or PVC tubing, and polypropylene or PVC infusion bags:

- sodium chloride 0.9% solution;
- glucose 5% solution;
- sodium chloride 0.18% and glucose 4% solution;
- sodium chloride 0.45% and glucose 2.5% solution.

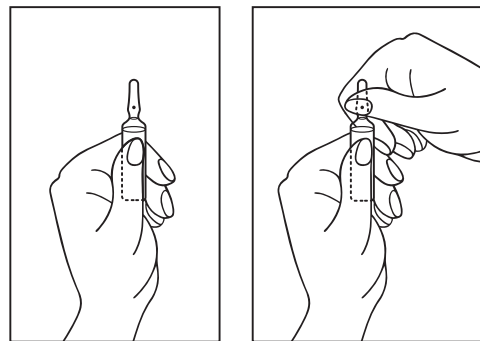
Cisatracurium has been shown to be compatible with the following commonly used perioperative drugs, when mixed in conditions simulating administration into a running intravenous infusion via a Y-site injection port: alfentanil hydrochloride, droperidol, fentanyl citrate, midazolam hydrochloride and sufentanil citrate.

Where other drugs are administered through the same needle or cannula as cisatracurium, it is recommended that each drug be flushed through with an adequate volume of a suitable intravenous fluid, e.g. sodium chloride 0.9% solution.

As with other drugs administered intravenously, when a small vein is selected as the injection site, cisatracurium should be flushed through the vein with a suitable intravenous fluid, e.g. sodium chloride 0.9% solution.

Instruction of ampoule opening

- 1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
- 2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).



Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Shelf life after dilution

Chemical and physical in-use stability has been demonstrated for 24 hours at 5°C and 25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 to 8°C.