

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 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, atracurium or benzenesulfonic acid or any of the other ingredients of this medicine (listed in section 6).

If any of the above apply to you tell your doctor or nurse before you are given 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;

- if you have severe acid-base and/or electrolyte imbalance;
- 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.

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

- anaesthetics (used to reduce sensation and pain during surgical procedures);
- certain other medicines to relax the muscles;
- 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.

An adverse impact of cisatracurium on the breastfed child cannot be excluded, however it is not expected if breastfeeding is restarted after the effects of the substance have worn off. Cisatracurium is quickly eliminated from the body. Women should abstain from breastfeeding for 3 hours after the treatment discontinuation.

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.

Allergic reactions (may affect up to 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 (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

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

Very rare (may affect up to 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. 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.

Shelf life after dilution

Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C and 25°C.

From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of user.

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 with one point cut.
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 and Manufacturer

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Latvia	Cisatracurium Kalceks 2 mg/ml šķīdums injekcijām/infūzijām
Austria	Cisatracurium Kalceks 2 mg/ml Injektions-/Infusionslösung
Belgium	Cisatracurium Kalceks 2 mg/ml, solution injectable/pour perfusion Cisatracurium Kalceks 2 mg/ml, oplossing voor injectie/infusie Cisatracurium Kalceks 2 mg/ml, Injektions-/Infusionslösung
Czech Republic	Cisatracurium Kalceks
Denmark	Cisatracurium Kalceks
Estonia	Cisatracurium Kalceks
France	CISATRACURIUM KALCEKS 2 mg/ml, solution injectable/pour perfusion
Germany	Cisatracurium Kalceks 2 mg/ml Injektions-/Infusionslösung
Hungary	Cisatracurium Kalceks 2 mg/ml oldatos injekció/infúzió

Ireland	Cisatracurium 2 mg/ml solution for injection/infusion
Italy	Cisatracurio Kalceks
Lithuania	Cisatracurium Kalceks 2 mg/ml injekcinis ar infuzinis tirpalas
Norway	Cisatracurium Kalceks
Poland	Cisatracurium Kalceks
Spain	Cisatracurio Kalceks 2 mg/ml solución inyectable y para perfusión EFG

This leaflet was last revised in 02/2022

The following information is intended for healthcare professionals only:

Incompatibilities

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 is physically and chemically stable for 24 hours at 2-8°C and 25°C at concentration 0.1 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 9 mg/ml (0.9%) solution for injection;
- glucose 50 mg/ml (5%) solution for injection;
- sodium chloride 1.8 mg/ml (0.18%) and glucose 40 mg/ml (4%) solution for injection;
- sodium chloride 4.5 mg/ml (0.45%) and glucose 25 mg/ml (2.5%) solution for injection.

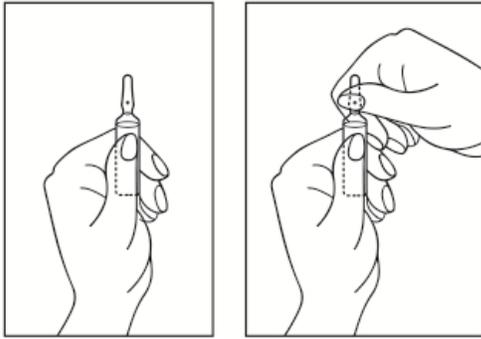
Cisatracurium has been shown to be compatible with the following commonly used perioperative drugs, when mixed in conditions simulating administration into a running intravenous infusion via a Y-site injection port: alfentanil hydrochloride, droperidol, fentanyl citrate, midazolam hydrochloride and sufentanil 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 9 mg/ml (0.9%) solution for injection.

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 9 mg/ml (0.9%) solution for injection.

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.