Package Leaflet: Information for the User
Cisatracurium 2 mg/ml solution for injection/infusion
Cisatracurium 5 mg/ml solution for injection/infusion
cisatracurium

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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
Do not use Cisatracurium:
- if you are allergic (hypersensitive) to cisatracurium, any other muscle relaxant or any other ingredients in Cisatracurium (listed in section 6)
- if 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 take Cisatracurium.

Warnings and precautions
Talk to your doctor, nurse or pharmacist before you are given this medicine if:
- you have muscle weakness, tiredness or difficulty in co-ordinating your movements (*myasthenia gravis*)
- you have a neuromuscular disease, such as a muscle wasting disease, paralysis, motor neurone disease or cerebral palsy
- 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, nurse or pharmacist before you are given Cisatracurium.

Other medicines and Cisatracurium
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, **including medicines obtained without a prescription**.
In particular tell your doctor if you are taking any of the following:
- anaesthetics (used to reduce sensation and pain during surgical procedures)
- antibiotics (used to treat infections)
- medicines for uneven heart beats (anti-arrhythmics)
- 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, monoamine oxidase inhibitors (MAOIs) or chlorpromazine (which can also be used for sickness)
- medicines containing magnesium
- medicines 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 taking 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 to take Cisatracurium

How your injection 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 medicine is slowly given to you over a long period of time.

Your doctor will decide the way you are given the medicine 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
Cisatracurium 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 (affects less than 1 in 10,000 people)
If you have an allergic reaction, **tell your doctor or nurse straight away**. 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, nurse or pharmacist if you experience any of the following symptoms

Common (affects 1 to 10 users in 100):

- decrease in heart rate
- decrease in blood pressure.

Uncommon (affects 1 to 10 users in 1,000):

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

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

- weak or aching muscles.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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.

Do not use this medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C- 8°C). Do not freeze.

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

This product should be used immediately after reconstitution.
If diluted, store the infusion solution between 2°C and 8°C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.

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.

Each ml contains 2 mg cisatracurium (as 2,68 mg of cisatracurium besylate).
Each ml contains 5 mg cisatracurium (as 6,69 mg of cisatracurium besylate).

- The other ingredients are benzene sulfonic acid and water for injection.

What Cisatracurium looks like and contents of the pack
Colourless to pale yellow or greenish yellow clear solution.

Cisatracurium 2 mg/ml solution for injection/infusion is supplied in 2.5 ml, 5.0 ml and 10 ml transparent glass (type I) ampoules each containing 5, 10 and 20 mg of cisatracurium respectively. The ampoules are packaged in a cardboard box with an instruction leaflet.
Pack sizes of 1 and 5 ampoules.

Cisatracurium 5 mg/ml solution for injection/infusion is supplied in 30 ml clear glass (type I) vial containing 150 mg of cisatracurium. The glass vial is sealed with a rubber stopper and an aluminium flip cap and packaged in a cardboard box with an instruction leaflet.
Pack size of 1, 5 and 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire EN6 1TL, UK.

Manufacturer
Laboratorio Reig Jofré,
S.A. Gran Capitán,
10, Sant Joan Despí,
08970 Barcelona, Spain

Or

Viatris Santé
1 rue de Turin, 69007 Lyon, France

Or

Viatris UK Healthcare Limited,
Building 20, Station Close, Potters Bar, EN6 1TL, United Kingdom

Or
For Cisatracurium 2 mg/ml solution for injection/infusion only
Vianex S.A.,
12 Km National Road Athens Lamia, Metamorfossi, 144 51, Greece

This leaflet was last revised in November 2025

The following information is intended for medical or healthcare professionals only
Instructions for use
This product is for single use only. Use only colourless to pale yellow or greenish yellow clear solution. The product should be visually inspected before use, and if the visual appearance has changed or if the container is damaged, the product must be discarded.

Diluted Cisatracurium is physically and chemically stable for at least 24 hours at 5°C and 25°C at concentrations between 0.1 and 2 mg/mL in the following infusion fluids, in either polyvinyl chloride or polypropylene containers:

- Sodium Chloride (0.9% w/v) Intravenous Infusion.
- Glucose (5% w/v) Intravenous Infusion.
- Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion.
- Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion.

However, since the product contains no antimicrobial preservative, dilution should be carried out immediately prior to use, or failing this be stored as directed below:

Chemical and physical in-use stability has been demonstrated for at least 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 would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Cisatracurium has been shown to be compatible with the following commonly used peri-operative 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 indwelling 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 Intravenous Infusion (0.9% w/v).

As with other medicinal products 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 intravenous infusion (0.9% w/v).