

Package leaflet: Information for the <patient> <user>

**Cisatracurium 2 mg/ml Solution for injection/ infusion
Cisatracurium 5 mg/ml Solution for injection/ infusion**

Cisatracurium

The name of your medicine are “Cisatracurium 2 mg/ml Solution for injection/ infusion” and “Cisatracurium 5 mg/ml Solution for injection/ infusion” but in the rest of the leaflet it will be called “Cisatracurium Injection 2 mg/ml” and “Cisatracurium Injection 5 mg/ml”.

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Cisatracurium Injection is and what it is used for

Cisatracurium Injection contains a medicine called cisatracurium. This belongs to a group of medicines called muscle relaxants.

Cisatracurium is an intermediate-duration, non-depolarising neuromuscular blocking agent for intravenous administration.

Cisatracurium Injection 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 Injection

Do not use Cisatracurium Injection if:

- you are allergic (hypersensitive) to cisatracurium, any other muscle relaxant or any of the other ingredients in Cisatracurium Injection (listed in Section 6)
- you have reacted badly to an anaesthetic before.

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

Take special care with Cisatracurium Injection

Talk to your doctor, nurse or pharmacist before having 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
- 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, nurse or pharmacist before you are given Cisatracurium Injection.

Other medicines and Cisatracurium Injection

Tell your doctor if you are taking or have recently taken any other medicines.

This includes any herbal products or medicines bought 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 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 taking this medicine.

As a precaution breast-feeding should be discontinued during treatment and for at least 24 hours after administration of this medicinal product.

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 Injection is given

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 Injection 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 Injection than you should

Cisatracurium Injection 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.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, Cisatracurium Injection 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 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.

Talk to your doctor, nurse or pharmacist 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cisatracurium Injection

- Keep Cisatracurium Injection out of the reach and sight of children.
- Do not use Cisatracurium Injection 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.
- 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. Your doctor or nurse will throw away any medicine that is no longer required. This will help protect the environment.

6. Contents of the pack and other information

What Cisatracurium Injection contains

- The active substance is 2 mg/ml or 5 mg/ml cisatracurium (as besilate).
- The other ingredients are benzene sulfonic acid and water for injections.

What Cisatracurium Injection looks like and contents of the pack

Cisatracurium Injection 2 mg/ml comes in:

- 2.5 ml clear glass vial contains 5 mg of cisatracurium (as cisatracurium besilate) and are supplied in packs of 1 and 5 vials
- 5 ml clear glass vial contains 10 mg of cisatracurium (as cisatracurium besilate) and are supplied in packs of 1 and 5 vials
- 10 ml clear glass vial contains 20 mg of cisatracurium (as cisatracurium besilate) and are supplied in packs of 1 and 5 vials
- 25 ml clear glass vial contains 50 mg of cisatracurium (as cisatracurium besilate) and are supplied in packs of 1 and 2 vials

Cisatracurium Injection 5 mg/ml comes in:

- 30 ml clear glass vial contains 150 mg of cisatracurium (as cisatracurium besilate) and are supplied in packs of 1 and 5 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Limited,
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United Kingdom

Manufacturer

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The Netherlands

This medicinal product is authorized in the Member States of the EEA under the following names:

Country	Proposed Name
Austria	Cisatracurium Accord 2 mg/ml Injektions-/Infusionslösung Cisatracurium Accord 5 mg/ml Injektions-/Infusionslösung
Belgium	Cisatracurium Accord Healthcare 2 mg/ml solution injectable/perfusion, oplossing voor injectie of infusie, Injektions-/Infusionslösung Cisatracurium Accord Healthcare 5 mg/ml solution injectable/perfusion, oplossing voor injectie of infusie, Injektions-/Infusionslösung
Cyprus	Cisatracurium Accord 2 mg/ml Solution for injection or infusion Cisatracurium Accord 5 mg/ml Solution for injection or infusion
Germany	Cisatracurium Accord 2 mg/ml Injektionslösung/ Infusionslösung Cisatracurium Accord 5 mg/ml Injektionslösung/ Infusionslösung
Spain	Cisatracurium Accord 2 mg/ml solución inyectable y para perfusión EFG Cisatracurium Accord 5 mg/ml solución inyectable y para perfusión EFG
Finland	Cisatracurium Accord 2 mg/ml injektio/infusioneste, liuos Cisatracurium Accord 5 mg/ml injektio/infusioneste, liuos
France	CISATRACURIUM ACCORD 2 mg/ml, solution injectable/pour perfusion CISATRACURIUM ACCORD 5 mg/ml, solution injectable/pour perfusion
Italy	Cisatracurio Accord
Lithuania	Cisatracurium Accord 2 mg/ml injekcinis/infuzinis tirpalas Cisatracurium Accord 5 mg/ml injekcinis/infuzinis tirpalas
Poland	Cisatracurium Accord
The Netherlands	Cisatracurium Accord 2 mg/ml oplossing voor injectie of infusie Cisatracurium Accord 5 mg/ml oplossing voor injectie of infusie
Portugal	Cisatracúrio Accord
United Kingdom	Cisatracurium 2 mg/ml Solution for injection/infusion Cisatracurium 5 mg/ml Solution for injection/infusion

This leaflet was last approved in

The following information is intended for healthcare professionals only

Cisatracurium 2 mg/ml Solution for injection/ infusion

Cisatracurium 5 mg/ml Solution for injection/ infusion

This medicinal product must not be mixed with other medicinal product except those mentioned in 'Instructions for use and handling' below.

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. It is not compatible with ketorolac, trometamol or propofol injectable emulsion.

Instructions for use and handling

For single use only.

Use only clear and almost colourless up to slightly yellow/greenish yellow coloured solutions. 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 Injection 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 PVC or non-PVC 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 the diluted solution should be stored as directed below.

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 dilution 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 this medicinal product, 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 drugs administered intravenously, when a small vein is selected as the injection site, Cisatracurium Injection should be flushed through the vein with a suitable intravenous fluid, e.g., sodium chloride intravenous infusion (0.9% w/v).

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