

PACKAGE LEAFLET

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse .
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Cisatracurium 2 mg/ml Solution for Injection/Infusion

In the rest of this leaflet Cisatracurium 2 mg/ml Solution for Injection/Infusion is called Cisatracurium.

What is in this leaflet:

1. What Cisatracurium is and what it is used for
2. What you need to know before you use Cisatracurium
3. How to use Cisatracurium
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

The active substance is cisatracurium besilate, which 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 use Cisatracurium

Do not use Cisatracurium if you:

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

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

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

Take special care with Cisatracurium

Check with your doctor, nurse or pharmacist before receiving 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 applies to you, talk to your doctor or nurse, before having Cisatracurium.

Other medicines and Cisatracurium

Please tell your doctor if you are taking or have recently taken 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.

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 to use 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 will be 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.

Use in children

Children less than 1 month old should not be given this medicine.

If you are given 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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:

For UK: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For IE: 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.
- 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.
- 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.
- Medicines should not be disposed of via wastewater or household waste. Your doctor or nurse will dispose of any medicine that is no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cisatracurium contains

- The active substance is cisatracurium (as besilate).
- The other ingredients are benzene sulfonic acid and water for injection.

What Cisatracurium looks like and contents of the pack

Cisatracurium in clear glass ampoule in a carton of 5 and carton of 1.

Each 10 ml ampoule contains 20 mg of cisatracurium.

Each 5 ml ampoule contains 10 mg of cisatracurium.

Each 2.5 ml ampoule contains 5 mg of cisatracurium.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.

Manufacturer: DEMO S.A., PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece.

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

UK: Cisatracurium 2 mg/ml Solution for Injection/Infusion

IE: Cisatracurium 2 mg/ml Solution for Injection/Infusion

EL: CISATRAL 2 mg/ml Διάλυμα για ένεση ή έγχυση

DE: Cisatracurium Noridem 2 mg/ml Injektionslösung/Infusionslösung

AT: Cisatracurium Noridem 2 mg/ml Injektionslösung/Infusionslösung

PL: Cisatracurium Noridem

This leaflet was last revised in 07/2021.

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The following information is intended for medical or healthcare professionals only

This product is 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 is physically and chemically stable for at least 24 hours at 5°C and 25°C at concentrations between 0.1 and 1 mg/mL in the following infusion fluids, or in 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 under section 6.3.

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: fentanyl citrate and midazolam hydrochloride. 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 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 intravenous infusion (0.9% w/v).

