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 using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

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
This medicine belongs to a group of medicines called muscle relaxants. The full name of this medicine is Cisatracurium solution for injection/infusion but for ease of reference it will be referred to as Cisatracurium throughout the leaflet.

Cisatracurium is used
- During surgery and other procedures and in intensive care
- With general anaesthesia, or sedation in the Intensive Care Unit to relax muscles
- To help insert a tube into the windpipe (tracheal intubation) if a person needs help to breathe (with or without a machine).

Cisatracurium is used in adults and in children over 1 month of age.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CISATRACURIUM
Do not use Cisatracurium
- If you are allergic (hypersensitive) to cisatracurium besilate, atracurium, or any of the ingredients in this medicine (listed in section 6)

Warnings and Precautions
Talk to your doctor before using this medicine if you:
- have a neuromuscular disease, such as a muscle wasting disease, paralysis, motor neurone disease, cerebral palsy or myasthenia gravis
- have a burn which requires medical treatment
- have ever had an allergic reaction to any muscle relaxant
- are aware that you have abnormal blood acidity or abnormal blood electrolyte levels

Using 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. This includes herbal medicines. This is because these medicines can affect how well Cisatracurium works or cause side effects.

In particular tell your doctor, nurse or pharmacist if you are taking, or have recently received 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 frusemide
- 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 nausea)
- medicines containing magnesium
- medicines for Alzheimer’s disease (anticholinesterases such as donepezil)
- other muscle relaxants

**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 using this medicine.

You should not be given this medicine if you are pregnant.

If you are breast-feeding and you are given this medicine because of a medical emergency, ask your doctor for advice before starting breast-feeding again. Breast-feeding may be started 12 hours after this medicine has been given to you.

**Driving and using machines**
Some patients may occasionally feel dizzy, drowsy or confused after treatment with this medicine. If this happens to you, do not drive or use machinery. Your doctor will advise how long you should wait after an operation before you can drive.

### 3. HOW TO USE CISATRACURIUM

**Cisatracurium will be administered to you by a healthcare professional.**

This medicine will only be administered directly into a vein, either by injection or by slow intravenous infusion. Cisatracurium can be given as a single injection into your vein (intravenous bolus injection) or as a continuous infusion into your vein. This is where the drug is slowly given to you over a longer period of time.

Your doctor will decide how you are given this medicine and the dose you will receive. This depends on the following factors:
- 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 receive more Cisatracurium than you should**
This medicine will always be given by your doctor or anaesthetist under carefully controlled conditions. It is unlikely that you will be given too much, however, tell your doctor or nurse if you have any concerns.

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 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

The following side effects have been reported following the administration of this medicine:

**Common (may affect up to 1 in 10 people):**
- decreased heart rate
- low blood pressure

**Uncommon (may affect up to 1 in 100 people):**
- a rash or redness on your skin
- coughing or wheezing

**Very rare (may affect up to 1 in 10,000 people):**
- muscle wasting and muscle weakness
- 

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 pharmacist.

**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:

Yellow Card Scheme
Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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 carton and the label. The expiry date refers to the last day of that month.

Store in a refrigerator between 2 – 8°C. Do not freeze. Keep the vial in the outer carton in order to protect from light.

To be used only if the solution appears clear and almost colourless to slightly yellow/greenish colour. The product should be visually inspected before use, and if the visual appearance
differs from the above description or if the container is damaged, the product must be discarded.

Unused portions of opened vials must not be stored for later use.

Diluted solutions should be used immediately, however, if this is not possible they can, in certain circumstances, be stored for up to 24 hours.

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. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cisatracurium contains
- The active substance is cisatracurium besilate.
  - Each 2.5 ml vial contains 5 mg cisatracurium (as cisatracurium besilate)
  - Each 5 ml vial contains 10 mg cisatracurium (as cisatracurium besilate)
  - Each 10 ml vial contains 20 mg cisatracurium (as cisatracurium besilate)
  - Each 30 ml vial contains 150 mg cisatracurium (as cisatracurium besilate)
- The other ingredients are benzenesulfonic acid and Water for Injections.

What this medicine looks like and the contents of the pack
Cisatracurium is a colourless to pale yellow/greenish yellow solution which comes in glass containers called vials. This medicine may be supplied in packs containing 1 or 5 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Hospira UK Limited
Horizon,
Honey Lane,
Hurley,
Maidenhead,
SL6 6RJ,
United Kingdom

Manufacturers responsible for batch release
Avara Lisca Pharmaceutical Services S.p.A.
Via Fosse Ardeatine, 2
20060 Liscate (MI)
Italy

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The following information is intended for medical or healthcare professionals only

Incompatibilities

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.

The diluted product is stable for at least 24 hours at concentrations between 0.1 – 2.0 mg/ml in the following infusion solutions:

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

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 should be flushed through the vein with a suitable intravenous fluid, e.g., sodium chloride intravenous infusion (0.9% w/v).

Shelf life after dilution

Shelf life after dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 5°C and 25°C at concentrations of 0.1 and 2 mg/ml in PVC infusion bags.

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°C - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.