

FRONT SIDE

If any adverse event occurred, please report to us via:

Email: drugsafety@themismedicare.com
Link to download form -
<https://www.themismedicare.com/adverse-events/>

e) HOW TO STORE CISATRA (CISATRACURIUM BESYLATE INJECTION USP)

Keep out of the reach and sight of children.

Store in a refrigerator (2°C to 8°C), protected from freezing and light.

Do not use Cisatracurium Besylate Injection USP after the expiry date which is stated on the label and carton, after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice an unclear solution and extraneous particles or if the container is damaged.

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.

f) FURTHER INFORMATION

What CISATRA (Cisatracurium Besylate Injection USP) contains

The active substance is Cisatracurium Besylate USP.

The other ingredient(s) are Benzene Sulphonic Acid, Water for Injections (CISATRA 5 ml pack).

The other ingredient(s) are Benzene Sulphonic Acid (for pH adjustment), Benzyl Alcohol USP-NF (CISATRA 10 ml pack).

What CISATRA (Cisatracurium Besylate Injection USP) looks like and contents of the pack

This medicine is a clear colourless liquid.

Cisatra 2 mg/ml available in
5 ml amber glass vial in a box
10 ml amber glass vial in a box

MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder: Themis Medicare Limited

Address: : 11/12, Udyog Nagar,
S.V. Road, Goregaon (West),
Mumbai-400104

Country: : India

Telephone: : 91-22-67607080

E-Mail: :

themis@themismedicare.com

Manufacturer:

THEMIS

M/s Themis Medicare Limited

Address: : Sector 6A, Plot No. 16,17 &
18, IIE, SIDCUL,
HARIDWAR-249 403,
Uttarakhand.

Country: : India

Telephone: : 91-1334-239322/21

E-Mail: :

hwqualityhead@themismedicare.com

This leaflet was last approved on: NA

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Cisatracurium Besylate Injection USP

CISATRA 2 mg/ml Vial

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, health care provider 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

- What is **CISATRA** (Cisatracurium Besylate Injection USP) and what it is used for
- Before you use **CISATRA** (Cisatracurium Besylate Injection USP)
- How to use **CISATRA** (Cisatracurium Besylate Injection USP)
- Possible side effects
- How to store **CISATRA** (Cisatracurium Besylate Injection USP)
- Further information

a) WHAT IS CISATRA (CISATRACURIUM BESYLATE INJECTION USP) AND WHAT IT IS USED FOR

CISATRA (Cisatracurium Besylate Injection USP) contains a medicine called Cisatracurium Besylate. This belongs to a group of medicines called muscle relaxants. Cisatracurium Besylate is a highly selective, competitive or non-depolarising neuromuscular blocking agent.

Cisatracurium Besylate Injection USP is an intermediate-onset/ intermediate - duration neuromuscular blocking agent indicated for inpatients and outpatients as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation in the ICU

Cisatracurium Besylate Injection USP is used for below:

- for inpatients and outpatients as an adjunct to general anesthesia.
- to help insert a tube into the windpipe (tracheal intubation), if a person needs help to breathe
- to relax muscles during surgery or mechanical ventilation in the intensive care (ICU)

Ask your doctor if you would like more explanation about this medicine.

b) BEFORE YOU USE CISATRA (CISATRACURIUM BESYLATE INJECTION USP)

Do not take Cisatracurium Besylate Injection USP

- if you are allergic to Cisatracurium Besylate, any other muscle relaxant or any of the other ingredients in Cisatracurium Besylate Injection USP (listed in section *Further Information*)
- if you have reacted badly to an anaesthetic before.

Do not use in premature infants due to the presence of benzyl alcohol in the formulation. Do not take Cisatracurium Besylate Injection USP if any of the above applies to you.

350 mm

PP21CEXP0000

120 mm

BACK SIDE

If you are not sure, talk to your doctor, nurse or pharmacist before you have Cisatracurium Besylate Injection USP.

Take special care with Cisatracurium Besylate Injection USP

Talk to your doctor or pharmacist before receiving Cisatracurium Besylate Injection USP.

- If you have a neuromuscular disease, such as a e.g., myasthenia gravis and the myasthenic syndrome, carcinomatosis).
- If you have a burn which requires medical treatment
- If you have hemiparesis or paraparesis
- If you have ever had an allergic reaction to any muscle relaxant which was given as part of an operation
- If you have renal or hepatic disease, renal dysfunction or in patients with end-stage liver disease
- If you have Malignant Hyperthermia
- If Patient is neonates should not have this medicine (medicine containing benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis)
- 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 Besylate Injection USP.

Taking Other medicines and Cisatracurium Besylate

Please Tell your doctor, health care provider or pharmacist if you are receiving or have recently taken any other medicines. This includes medicines obtained without a prescription.

In particular tell your doctor, nurse or pharmacist if you are receiving any of the following

- skeletal muscle relaxant (e.g succinylcholine)
- halogenated inhalational anesthetic agent (e.g Isoflurane or enflurane)
- antibiotics (used to treat infections) (e.g., aminoglycosides, tetracyclines, bacitracin, polymyxins, lincomycin, clindamycin, colistin, and sodium colistemetate), local anesthetics,
- medicines for fits (epilepsy), such as phenytoin or carbamazepine
- medicines containing magnesium salts, lithium,
- anti-arrhythmics (medicines for uneven heart beats) (e.g procainamide, and quinidine.)

Taking Cisatracurium Besylate with food and drink

There is no known alcohol/food interactions with Cisatracurium Besylate Injection USP. This does not necessarily mean no interactions exist. Always consult your healthcare provider.

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 or pharmacist for advice before having 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.

Driving and using machines

It can be dangerous to drive or operate machinery too soon after having had an operation. Your doctor will tell you how long to wait before you can drive and use machinery.

c) HOW TO USE CISATRA (CISATRACURIUM BESYLATE INJECTION USP)

How Cisatracurium Besylate Injection USP 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 Besylate Injection USP will be administered to you by a healthcare professional

Cisatracurium Besylate Injection USP 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 take more Cisatracurium Besylate Injection USP than you should Cisatracurium Besylate Injection USP 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 forget to take Cisatracurium Besylate Injection USP

It is unlikely that a dose of Cisatracurium Besylate Injection USP will be missed if you are monitored in a healthcare setup. However, if you have missed taking a dose of the injection, inform the doctor or nurse immediately.

If you stop taking Cisatracurium Besylate Injection USP

Do not start, stop, or change the dose of medicine without checking with your doctor

d) POSSIBLE SIDE EFFECTS

Like all medicines, Cisatracurium Besylate Injection USP 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.

The following adverse effects have a possible causal relationship to Cisatracurium Besylate Injection USP (incidence less than 1%):

Cardiovascular System: Flushing (0.2%), hypotension (0.2%), and bradycardia (0.4%).

Respiratory System: Bronchospasm (0.2%).

Dermatological: Rash (0.1%).

Talk to your doctor, nurse or pharmacist if you notice any of the following:

General

Histamine release, hypersensitivity reactions including anaphylactic or anaphylactoid reactions, which in some cases have been life threatening and fatal.

There are rare reports of wheezing, laryngospasm, bronchospasm, rash and itching following administration of cisatracurium besylate in children.

These reported adverse events were not serious and their etiology could not be established with certainty.

Musculoskeletal:

Prolonged neuromuscular block, Sinadequate neuromuscular block, muscle weakness, and myopathy.

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

350 mm

120 mm