APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CISATRACURIUM 5 mg/2,5 ml FRESENIUS

CISATRACURIUM 10 mg/5 ml FRESENIUS

CISATRACURIUM 20 mg/10 ml FRESENIUS

Solution for injection or infusion (2 mg/ml)

Cisatracurium

Sugar free

Read all of this leaflet carefully before you start using CISATRACURIUM FRESENIUS 2 mg/ml

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- CISATRACURIUM FRESENIUS 2 mg/ml has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What CISATRACURIUM FRESENIUS 2 mg/ml is and what it is used for
2. What you need to know before you are given CISATRACURIUM FRESENIUS 2 mg/ml
3. How CISATRACURIUM FRESENIUS 2 mg/ml is given

05/03/2021

4. Possible side effects

5. How to store CISATRACURIUM FRESENIUS 2 mg/ml

6. Contents of the pack and other information

1. What CISATRACURIUM FRESENIUS 2 mg/ml is and what it is used for

CISATRACURIUM FRESENIUS 2 mg/ml contains a medicine called cisatracurium. It belongs to a group of medicines called muscle relaxants.

CISATRACURIUM FRESENIUS 2 mg/ml is used:

- to relax muscles during surgical procedures;
- to help insert a tube into the windpipe (tracheal intubation), if a person needs help/assistance to breathe.

2. What you need to know before you are given CISATRACURIUM FRESENIUS 2 mg/ml

CISATRACURIUM FRESENIUS 2 mg/ml should not be administered to you:

- if you are hypersensitive (allergic) to cisatracurium any other muscle relaxant or any other ingredients in CISATRACURIUM FRESENIUS 2 mg/ml (listed in section 6);
- if you have reacted badly to an anaesthetic before;
- if you are pregnant or breastfeeding, as use and safe use in pregnancy and lactation have not been established.

No data are available for the safe use in new-born babies and CISATRACURIUM FRESENIUS 2 mg/ml should therefore not be given to new-born babies.

05/03/2021

Warnings and precautions

Talk to your doctor or healthcare provider before being given CISATRACURIUM FRESENIUS 2 mg/ml if:

- 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 FRESENIUS 2 mg/ml;
- you have muscle weakness, tiredness or difficulty in coordinating your movements (myasthenia gravis);
- you have a neuromuscular disease, such as a muscle wasting disease, paralysis, motor neuron disease or cerebral palsy;
- you have a burn which requires medical treatment;
- you have a severe acid-base and/or electrolyte disorder.

Other medicines and Cisatracurium Fresenius 2 mg/ml

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular tell your doctor if you are taking any of the following:

- anaesthetics (used to reduce sensation and pain during surgical procedures);
- other muscle relaxants such as suxamethonium;
- antibiotics (used to treat infections), such as aminoglycosides, polymyxins, spectinomycin, tetracyclines, lincomycin and clindamycin;

05/03/2021

- medicines for uneven heart beats (antidysrhythmics), such as propranolol, oxprenolol, calcium channel blockers, lidocaine, procainamide and quinidine;
- medicines for high blood pressure such as propranolol;
- water tablets (diuretics), such as furosemide, mannitol and acetazolamide;
- 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 breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using CISATRACURIUM FRESENIUS 2 mg/ml.

Use and safety in pregnancy and breastfeeding have not been established.

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.

05/03/2021

3. How to use Cisatracurium Fresenius 2 mg/ml

How your injection is given

You will not be expected to give yourself CISATRACURIUM FRESENIUS 2 mg/ml. It will be given to you by a person who is qualified to do so.

CISATRACURIUM FRESENIUS 2 mg/ml 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.

Your doctor will decide on how often you should receive the dose based on your condition.

The duration of treatment will be determined by your doctor.

Children less than 1 month old should not have CISATRACURIUM FRESENIUS 2 mg/ml.

If you receive more Cisatracurium Fresenius 2 mg/ml than you should

Since a healthcare provider will administer CISATRACURIUM FRESENIUS 2 mg/ml he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

05/03/2021

If you stop using Cisatracurium Fresenius 2 mg/ml

Since a healthcare provider will administer CISATRACURIUM FRESENIUS 2 mg/ml, it is unlikely that the dose will be missed.

4. Possible side effects

CISATRACURIUM FRESENIUS 2 mg/ml can have side effects.

Not all side effects reported for CISATRACURIUM FRESENIUS 2 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CISATRACURIUM FRESENIUS 2 mg/ml, please consult your healthcare provider for advice.

If any of the following happens, stop using CISATRACURIUM FRESENIUS 2 mg/ml and tell your doctor immediately:

Allergic reactions - 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to CISATRACURIUM FRESENIUS 2 mg/ml. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- decrease in heart rate;

05/03/2021

- decrease in blood pressure.

Less frequent side effects:

- a rash or redness of your skin;
- wheezing or coughing.
- weak or aching muscles.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CISATRACURIUM FRESENIUS 2 mg/ml

5. How to store Cisatracurium Fresenius 2 mg/ml

Store all medicines out of reach of children.

Store in a refrigerator (2°C- 8°C). Do not freeze. Store in the original package in order to protect from light. CISATRACURIUM FRESENIUS 2 mg/ml should be used immediately after reconstitution.

CISATRACURIUM FRESENIUS 2 mg/ml is for single use only.

Do not use this CISATRACURIUM FRESENIUS 2 mg/ml after the expiry date which is stated on the pack after 'Exp'. The expiry date refers to the last day of that month.

05/03/2021

If diluted, store the infusion solution in the refrigerator between 2 °C and 8 °C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Cisatracurium Fresenius 2 mg/ml contains

- The active substance is cisatracurium. Each ml contains 2 mg cisatracurium (as the besilate).
- The other ingredients are benzenesulphonic acid 1 % m/m (for pH adjustment) and water for injection (solvent).

What Cisatracurium Fresenius 2 mg/ml looks like and contents of the pack

Solution for injection or infusion.

A clear, pale yellow or greenish yellow solution, practically free from particles.

CISATRACURIUM FRESENIUS 2 mg/ml solution for injection/infusion is supplied in Type 1, clear, colourless glass ampoules:

- 5 mg in 2,5 ml: 1, 5, 10 or 50 3 ml-ampoules.
- 10 mg in 5 ml: 1, 5, 10 or 50 in 5 ml-ampoules.
- 20 mg in 10 ml: 1, 5, 10 or 50 in 10 ml-ampoules.

The ampoules are packaged in a cardboard box with an instruction leaflet.

Not all pack sizes may be marketed.



05/03/2021

Holder of Certificates of Registration

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House extension 7, Midrand

1685

South Africa

Tel no.: +2711 545 0000

The leaflet was last revised in

Registration numbers

Cisatracurium 5 mg/2,5 ml Fresenius: 47/17.1/0292

Cisatracurium 10 mg/5 ml Fresenius: 47/17.1/0292

Cisatracurium 20 mg/10 ml Fresenius: 47/17.1/0292

Access to the corresponding Professional Information

To be obtained from SAHPRA website: https://www.sahpra.org.za/Publications/

05/03/2021