

FINAL APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CISTRAX 5 mg/2,5 ml (Solution for injection or infusion)

CISTRAX 10 mg/5 ml (Solution for injection or infusion)

CISTRAX 150 mg/30 ml (Solution for injection or infusion)

Cisatracurium

Read all of this leaflet carefully before you are given CISTRAX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or~~ pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What CISTRAX is and what it is used for
2. What you need to know before you are given CISTRAX
3. How CISTRAX will be administered to you
4. Possible side effects
5. How CISTRAX is stored
6. Contents of the pack and other information

1. WHAT CISTRAX IS AND WHAT IT IS USED FOR

CISTRAX belongs to a group of medicines called muscle relaxants.

CISTRAX is used in adults and children over 1 month old:

- to relax muscles during operations,
- to help insert a tube into the windpipe (tracheal intubation), if a person needs help to breath.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CISTRAX

You should not be given CISTRAX:

- if you are hypersensitive (allergic) to cisatracurium, atracurium or any of the other ingredients of CISTRAX, listed in section 6.
- if you are pregnant and/or breastfeeding your baby.
- if your baby is younger than 1 month old.

Warnings and precautions

Special care should be taken with CISTRAX:

CISTRAX WORKS BY PARALYSING THE MUSCLES, INCLUDING MUSCLES THAT ASSIST WITH BREATHING BUT IT HAS NO EFFECT ON LEVEL OF CONSCIOUSNESS OR YOUR LEVEL OF PAIN TOLERANCE.

CISTRAX SHOULD ONLY BE ADMINISTERED BY AN ANAESTHETIST OR OTHER SUITABLY QUALIFIED HEALTHCARE PROVIDER AND ONLY IN AN AREA WHERE THE REQUIRED EQUIPMENT FOR MONITORING AND ASSISTING VENTILATION IS AVAILABLE.

(Tell your doctor or healthcare professional before being given CISTRAX):

- if you have ever had an allergic reaction to any muscle relaxant.
- if you have muscle weakness, tiredness or difficulty in co-ordinating your movements (myasthenia gravis).
- if 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.

Children and adolescents

CISTRAX should not be used in babies younger than 1 month old.

Other medicines and CISTRAX

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

Some medicines can interfere with CISTRAX which may increase its effect such as:

- anaesthetics (used to reduce sensation and pain during surgical procedures).
- other medicines that work the same way as CISTRAX.
- antibiotics (used to treat infections).
- medicines for irregular heart beats (antidysrhythmics).
- medicines for high blood pressure (such as calcium-channel blockers).
- water tablets (diuretics), such as furosemide.
- medicines containing magnesium salts.
- lithium used to treat depression.
- medicine that blocks muscle contraction (trimetaphan and hexamethonium).

Some medicines can interfere with CISTRAX which may decrease its effect such as:

- medicines for fits (epilepsy), such as phenytoin or carbamazepine.
- medicines that reverse the effect of CISTRAX (anticholinesterases).
- medicines that suppress the immune system used during organ transplants (azathioprine).

Other effects:

- medicines used to reduce bleeding during complex surgery (aprotinin) used with CISTRAX can cause breathing difficulties (apnoea).
- medicines for inflammation of the joints, such as chloroquine or d-penicillamine, steroids, medicines for mental illness, such as lithium or chlorpromazine (which can also be used for feeling sick) and medicines for Alzheimer's disease (anticholinesterases e.g. donepezil) may aggravate muscle weakness when used with CISTRAX.

Pregnancy and Breastfeeding:

You should not receive CISTRAX if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given CISTRAX.

Driving and using machinery:

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 risky to drive too soon after having an operation.

CISTRAX can cause you to have low blood pressure or weaken your muscles. You should not drive or use machinery if you are experiencing any of these side effects.

It is not always possible to predict to what extent CISTRAX may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CISTRAX affects you.

3. HOW CISTRAX WILL BE ADMINISTERED TO YOU

You will not be expected to give yourself CISTRAX. It will be given to you by a person who is qualified to do so.

The dosage you will receive will be determined by a doctor who will calculate the dosage according to your weight.

CISTRAX will be given to you as an injection into your vein or as a continuous infusion into your vein over a period of time.

If you receive more CISTRAX than you should:

Since a healthcare professional will administer CISTRAX, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. POSSIBLE SIDE EFFECTS

CISTRAX can have side effects.

Not all side effects reported for CISTRAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given CISTRAX or after, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately since you may need urgent medical attention:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

These are all very serious reactions. If you have them, you may have had a serious allergic reaction to CISTRAX.

Tell your doctor immediately if you notice any of the following:

- changes in the way your heart beats, for instance if you notice it beating slower,
- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following less frequent side effects:

- low blood pressure,
- constipation,
- a skin rash or reddening of the skin
- muscle weakness
- low body temperature or feeling cold (hypothermia)

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 “Adverse drug reaction and quality problem reporting form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>.

By reporting side effects, you can help provide more information on the safety of CISTRAX.

5. HOW CISTRAX IS STORED

Before dilution:

Store between 2 – 8 °C. Do not freeze.

Keep vials in outer carton in order to protect from light.

After dilution:

From a microbiological point of view, CISTRAX 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 – 8 °C or at or below 25 °C, unless dilution has taken place in controlled and validated aseptic conditions.

For single use only.

Discard any remaining solution.

Do not use after the expiry date stated on the label. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

Store all medicines out of reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CISTRAX contains

- The active substance is cisatracurium.
- The other ingredients are benzene sulphonic acid and water for injection.

What CISTRAX looks like and contents of the pack:

CISTRAX is a clear colourless to slightly yellow or greenish yellow solution, free from visible particles.

CISTRAX 5 mg/2,5 ml is filled into a 2 ml USP type I clear glass vial closed with a 13 mm grey, bromobutyl RTS rubber stopper and sealed with a red 13 mm aluminium flip-off seal, packed in an outer carton containing 5 vials.

CISTRAX 10 mg/5 ml is filled into a 6 ml USP type I clear glass vial closed with a 20 mm grey, bromobutyl RTS rubber stopper and sealed with a green 20 mm aluminium flip-off seal, packed in an outer carton containing 5 vials.

CISTRAX 150 mg/30 ml is filled into a 30 ml USP type I clear glass vial closed with a 20 mm grey, bromobutyl RTS rubber stopper and sealed with a green 20 mm aluminium flip-off seal, packed in an outer carton containing a single vial.

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd.

Building 31, Ground Floor,

Woodlands Office Park,

20 Woodlands Drive, Woodmead,

Johannesburg, 2191

Tel: +27 11 234 5701/2

Email: medinfo@accordhealth.co.za

This leaflet was last revised in

01 November 2024

REGISTRATION NUMBER

CISTRAX 5 mg/2,5 ml: 50/17.1/0131

CISTRAX 10 mg/5 ml: 50/17.1/0132

CISTRAX 150 mg/30 ml: 50/17.1/0133