1.3.2. PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NIMBEX 2 mg/ml 2,5 ml Injection

Cisatracurium 2 mg/ml, as the besylate

Sugar free

NIMBEX 2 mg/ml 5 ml Injection

Cisatracurium 2 mg/ml, as the besylate

Sugar free

NIMBEX 2 mg/ml 10 ml Injection

Cisatracurium 2 mg/ml, as the besylate

Sugar free

NIMBEX 5 (5 mg/ml) Injection

Cisatracurium 5 mg/ml, as the besylate

Sugar free

Read all of this leaflet carefully before NIMBEX is administered to you

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

What is in this leaflet

1. What NIMBEX is and what it is used for
2. What you need to know before NIMBEX is administered to you
3. How NIMBEX is administered to you
4. Possible side effects
5. How to store NIMBEX
6. Contents of the pack and other information

1. What NIMBEX is and what it is used for

NIMBEX belongs to a group of medicines called muscle relaxants.

NIMBEX is used during surgical procedures to relax muscles and help with controlled ventilation (breathing).

NIMBEX is also used to help insert a tube into the windpipe (endotracheal intubation) if a person requires help breathing.

2. What you need to know before NIMBEX is administered to you

NIMBEX should not be administered to you:

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

Warnings and precautions

Special care should be taken with NIMBEX:

NIMBEX PARALYSES THE MUSCLES THAT ASSIST WITH BREATHING AS WELL AS OTHER MUSCLES BUT HAS NO EFFECT ON ALERTNESS OR PAIN TOLERANCE.

NIMBEX INJECTION SHOULD ONLY BE ADMINISTERED BY OR UNDER THE SUPERVISON OF AN ANAESTHETIST OR OTHER HEALTHCARE PROVIDERS WHERE FACILITIES FOR ASSISTED VENTILATION (BREATHING) ARE AVAILABLE.

Tell your doctor or healthcare provider before being given the injection

- if you have previously had an allergic reaction to an anaesthetic before.
- if you have myasthenia gravis (muscle weakness, tiredness or difficulty in co-ordinating your movements).
- if you have neuromuscular disease (such as a muscle wasting disease or paralysis).
- if you have muscle twitching, hand tremor, muscle spasms, numbness and tingling, light headedness (these may be symptoms of severe acid-base or serum electrolyte abnormalities).
- if you have a burn that requires medical treatment.
- if you have had any injuries to the head (such as a violent blow, a cut or wound).
- if you have had hypoxic encephalopathy (a type of brain injury that occurs when the brain experiences a decrease in oxygen or blood flow).
- if you have or have had cerebral oedema (swelling of the brain that can cause headaches, neck pain or stiffness, dizziness and memory loss).

- if you have viral encephalitis (mild flu-like symptoms such as severe fever or headache, confusion, problems with sight or hearing).
- if you have known uraemia (feeling tired, feeling sick, loss of appetite, a metallic taste in the mouth and mental confusion)

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

Children

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

Other medicines and NIMBEX

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

Tell your doctor if you are taking or have been given any of the following:

- Enflurane, isoflurane, halothane, ketamine and suxamethonium (anaesthetics used to reduce sensation and pain during surgical procedures)
- Antibiotics such as aminoglycosides, polymyxins, spectinomycin, tetracyclines, lincomycin and clindamycin (used for treating infections)
- Antidysrhythmic medicines, such as propranolol, calcium channel blockers, lignocaine, procainamide and quinidine (medicines used for managing irregular heartbeats)
- Beta-blockers such as propranolol and oxprenolol (used to treat high blood pressure).
- Diuretics, such as furosemide, thiazides, mannitol and acetazolamide (water tablets).
- Magnesium salts (used for relieving muscle tension and supporting bone and skin health).
- Medicines containing lithium (used for treatment of depression).
- Ganglion blocking medicines such as trimetaphan and hexamethonium (used to produce controlled decreased blood pressure during surgery).
- Anti-rheumatic medicines such as chloroquine and D-penicillamine (used in treatment of rheumatoid arthritis).
- Neuroleptic medicines such as chlorpromazine (used in treatment of schizophrenia).

- Steroids.
- Antiepileptic medicines such as phenytoin and carbamazepine (used in the treatment of epilepsy).
- Anticholinesterases such as donepezil (used in the treatment of Alzheimers).

Pregnancy and breastfeeding

NIMBEX should not be administered to you if you are pregnant or 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 NIMBEX is administered to you.

Driving and using machines

NIMBEX will always be used in combination with a general anaesthetic and therefore your doctor will tell you how long to wait before you may drive or operate machinery. It can be dangerous to drive too soon after having an operation.

It is not always possible to predict to what extent NIMBEX 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 NIMBEX affects you.

3. How NIMBEX will be administered to you

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

NIMBEX 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 NIMBEX is administered to you. The dose you will receive 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 receive NIMBEX

If you receive more NIMBEX than you should

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

During an overdose you will experience muscle paralysis for a long period of time than expected.

If you forget to receive NIMBEX

Since a healthcare provider will administer NIMBEX, it is unlikely that the dose will be missed.

4. Possible side effects

NIMBEX can have side effects.

Not all side effects reported for NIMBEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while NIMBEX is being administered to you, please consult your healthcare provider for advice.

If any of the following happens, stop receiving NIMBEX and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are all very serious side effects. If you have them, you may have had a serious reaction to NIMBEX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following*:*

- bradycardia (decreased heart rate).

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common side effects:

- hypotension (decreased blood pressure).

Uncommon frequent side effects:

- cutaneous flushing (reddening of the skin),
- bronchospasm (tightening of the muscles in the bronchi that leads to wheezing and coughing).

Very rare side effects

- myopathy (muscle cramps, stiffness and spasm) and muscle weakness.

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: https://www.sahpra.org.za/health-productsvigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

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

5. How to store NIMBEX

Store all medicines out of reach of children.

Unopened vial/ampoule:

Store between 2 °C and 8 °C.

Do not freeze.

Protect from light.

Do not store in a bathroom.

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 (e.g. toilets).

In addition, the diluted solution can be stored at 5 °C or 25 °C.

This medicine is marketed as a single dose ampoule/vial and any unused portion of the solution must be discarded.

The ampoule/vial must not be removed from the outer carton until such time as it is required for administration.

6. Contents of the pack and other information

What NIMBEX contains

NIMBEX 2 mg/ml (2,5 ml) Injection:

The active substance is 2 mg/ml of cisatracurium, as the besylate

The other ingredients are water for injection and benzenesulfonic acid solution 32 % *w/v* (for pH adjustment).

Sugar free

NIMBEX 2 mg/ml (5 ml) Injection:

The active substance is 2 mg/ml of cisatracurium, as the besylate

The other ingredients are water for injection and benzenesulfonic acid solution 32 % *w/v* (for pH adjustment).

Sugar free

NIMBEX 2 mg/ml (10 ml) Injection

The active substance is 2 mg/ml of cisatracurium, as the besylate

The other ingredients are water for injection and benzenesulfonic acid solution 32 % *w/v* (for pH adjustment).

Sugar free

NIMBEX 5 mg/ml Injection

The active substance is 5 mg/ml of cisatracurium, as the besylate

The other ingredients are water for injection and benzenesulfonic acid solution 32 % *w/v* (for pH adjustment).

Sugar free

What NIMBEX looks like and contents of the pack

NIMBEX 2 mg/ml (2,5 ml) is a clear, pale yellow or greenish yellow solution, free from visible particulate matter.

NIMBEX 2 mg/ml (2,5 ml) Injection: Box of 5 ampoules.

NIMBEX 2 mg/ml (5 ml) is a clear, pale yellow or greenish yellow solution, free from visible particulate matter.

NIMBEX 2 mg/ml (5 ml) Injection: Box of 5 ampoules.

NIMBEX 2 mg/ml (10 ml) is a clear, pale yellow or greenish yellow solution, free from visible particulate matter.

NIMBEX 2 mg/ml (10 ml) Injection: Box of 5 ampoules.

NIMBEX 5 is a clear, pale yellow or greenish yellow solution, free from visible particulate matter.

NIMBEX 5: Box with one 30 ml vial.

Holder of Certificate of Registration

PHARMACARE LIMITED
Healthcare Park
Woodlands Drive
Woodmead 2191
Hotline: 0800 118 088 / +27 (0)11 239-6200

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24 February 2023

Registration numbers
NIMBEX 2 mg/ml (2,5 ml) Injection: 31/17.1/0255
NIMBEX 2 mg/ml (5 ml) Injection: 31/17.1/0444
NIMBEX 2 mg/ml (10 ml) Injection: 31/17.1/0445
NIMBEX 5 Injection: 31/17.1/0256

Access to the corresponding Professional Information
SAHPRA Repository of Professional Information and Patient Information Leaflets:
https://www.sahpra.org.za/pi-pil-repository/
Aspen Pharmacare:
E-mail: Medinfo@aspenpharma.com
Tel: 0800 118 088

NAMIBIA

Nimbex 2 mg/ml (2,5 ml): NS2 04/17.1/0929

Nimbex 2 mg/ml (5 ml): NS2 04/17.1/0928

Nimbex 2 mg/ml (10 ml): NS2 04/17.1/0927

Nimbex 5: NS2 04/17.1/0935

BOTSWANA

Nimbex 2 mg/ml (2,5 ml): S2 BOT1502681

Nimbex 2 mg/ml (5 ml): S2 BOT1502681A

Nimbex 2 mg/ml (10 ml): S2 BOT1502681B

ZIMBABWE

Nimbex 2 mg/ml (2,5 ml): PP 2014/1.3/4915

Nimbex 2 mg/ml (5 ml): PP 2014/1.3/4916

Nimbex 2 mg/ml (10 ml): PP 2014/1.3/4917

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