

Nimbex® Injection

cisatracurium besilate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NIMBEX. It does not contain all of the available information.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

Taking any medicine involves some risk. It is possible that all risks associated with this medicine might not have been detected, despite proper testing. Only your doctor or pharmacist is able to weigh up all of the relevant facts, and you should consult them if you have any queries.

If you have any concerns about the use of NIMBEX ask your doctor or pharmacist.

Keep this information.

You may want to read it again.

This leaflet provides information about NIMBEX. The statements that are made in this leaflet cannot be applied to any other medicine, even those that are similar or appear to contain the same ingredients.

What NIMBEX is used for

NIMBEX is used to relax the body's muscles. NIMBEX will normally be given to you when you are in surgery, or during other medical procedures. NIMBEX is only used in conjunction with an anaesthetic, so you will be asleep during the procedure.

If you have any questions about why NIMBEX is used ask your doctor.

How does NIMBEX work?

Cisatracurium besilate (the active ingredient in NIMBEX) belongs to a group of medicines called "neuromuscular blockers".

NIMBEX works by blocking the effects of one of the body's chemical messengers called acetylcholine. Acetylcholine is involved in muscle contraction.

By relaxing your body's muscles NIMBEX makes it easier for you to be kept asleep (under anaesthesia) or sedation.

Your doctor will be able to provide you with more information.

Before you use NIMBEX

NIMBEX is not suitable for everyone.

Before NIMBEX is used make sure that your doctor knows if:

- 1. You are allergic to:**
 - cisatracurium besilate, atracurium or benzenesulfonic acid.
 - any other muscle relaxants.
- 2. You are pregnant or breastfeeding.**
- 3. You suffer from myasthenia gravis, or any other form of neuromuscular disease.**
- 4. You, or a relative have had previous difficulties with anaesthetics.**

5. You are allergic to any other muscle relaxant medicine.

6. You are taking any other medication, including:

- Antibiotics
- Anti-arrhythmics, which are used to control irregular heart or rapid heart beat.
- Diuretics, used to increase your volume of urine.
- Magnesium or lithium salts.
- Phenytoin or carbamazepine (for fits).
- Any other medicine that you buy without a prescription from a pharmacy, supermarket or health food shop.

Your doctor will have a complete list of the medicines that may cause problems when taken with NIMBEX.

When NIMBEX must not be used

NIMBEX should not be used after the expiry date printed on the pack.

Using NIMBEX

NIMBEX is a medicine that is given by injection. NIMBEX will be administered by an anaesthetist or other highly trained doctor, usually during surgery or other medical procedures. The dosage will vary according to many factors such as body weight and the duration of the procedure.

If you have any questions about the dose that you will receive ask your doctor.

In case of overdose

Overdoses of NIMBEX lead to prolonged relaxation of the body's muscles. This can be readily treated, however, this situation is unlikely to occur because NIMBEX is only administered by an anaesthetist or other highly trained doctor who will closely monitor your progress.

After being treated with NIMBEX

Your doctor will be able to tell you whether there are any special instructions after you have been treated with NIMBEX.

Side effects

All medicines can have side effects. Sometimes they are serious. Most of the time they are not.

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have received NIMBEX.

It is possible that NIMBEX may cause the following side effects:

- Flushing of the face and upper body.
- Skin rashes.
- Slow heart beat.
- Low blood pressure.
- Difficulty breathing.

During studies using NIMBEX less than one patient in every 200 treated experienced these side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Other side effects not listed above may also occur in some people.

There is no evidence that NIMBEX is addictive.

Storage

NIMBEX should be stored by the hospital's pharmacy between 2° and 8°C and protected from light.

NIMBEX does not contain any antimicrobial preservative. When diluted, the preparation should be used immediately and any remaining solution must be discarded within 24 hours following dilution.

Product description

What NIMBEX looks like

NIMBEX is a pale yellow or greenish yellow solution.

NIMBEX Injection 2 mg/mL (all sizes) are presented in glass ampoules.

NIMBEX Injection 5 mg/mL is presented in glass vials.

Ingredients

NIMBEX Injection 2 mg/mL contains 2 mg cisatracurium besilate in every mL.

NIMBEX Injection 5 mg/mL contains 5 mg cisatracurium besilate in every mL.

NIMBEX also contains:

- benzenesulfonic acid
- water for Injections.

Sponsor:

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia.

Australian Registration Numbers:

- NIMBEX cisatracurium (as besylate) 5mg/2.5mL injection ampoule - AUST R 55913
- NIMBEX cisatracurium (as besylate) 10mg/5mL injection ampoule - AUST R 55931

- NIMBEX cisatracurium (as besilate) 150mg/30mL injection vial – AUSTR 55934

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