

Nimbex

cisatracurium

Nimbex 2 mg/ml solution for injection/infusion
Nimbex Forte 5 mg/ml solution for injection/infusion

Read all of this leaflet carefully before you are given 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.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Nimbex is and what it is used for
- 2 What you need to know before you are given Nimbex
- 3 How Nimbex is given
- 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 contains a medicine called cisatracurium. This belongs to a group of medicines called muscle relaxants.

Nimbex is used:

- to relax muscles during operations on adults and children over 1 month of age, including heart surgery
- to help insert a tube into the windpipe (tracheal intubation), if a person needs help to breathe
- to relax the muscles of adults in intensive care.

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

2 What you need to know before you are given Nimbex

Do not use Nimbex:

- if you are allergic to cisatracurium, any other muscle relaxant or any of the other ingredients in Nimbex (listed in section 6)
- you have reacted badly to an anaesthetic before.

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

Take special care with Nimbex

Talk to your doctor, nurse or pharmacist before having this medicine:

- if you have muscle weakness, tiredness or difficulty in co-ordinating your movements (myasthenia gravis)
- 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.
- 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 Nimbex.

Other medicines and Nimbex

Tell your doctor if you are taking or have recently taken any other medicines. This includes any herbal products or medicines bought without a prescription.

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

- anaesthetics (used to reduce sensation and pain during surgical procedures)
- antibiotics (used to treat infections)
- medicines for uneven heart beats (anti-arrhythmics)
- medicines for high blood pressure
- water tablets (diuretics), such as furosemide
- 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 or chlorpromazine (which can also be used for sickness)
- medicines containing magnesium
- drugs for Alzheimer's disease (anticholinesterases e.g. donepezil).

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 for advice before taking this medicine.

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.

3 How Nimbex is given

How your injection 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.

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 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 receive more Nimbex than you should

Nimbex 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 have any further questions on the use of this medicine, ask your doctor.

4 Possible side effects

Like all medicines, Nimbex 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.

Allergic reactions (affects less than 1 in 10,000 people)

If you have an allergic reaction, tell your doctor or nurse straight away. 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.

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

Common (affects less than 1 in 10 people)

- decrease in heart rate
- decrease in blood pressure.

Uncommon (affects less than 1 in 100 people)

- a rash or redness of your skin
- wheezing or coughing.

Very rare (affects less than 1 in 10,000 people)

- weak or aching muscles.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Nimbex

- Keep Nimbex out of the sight and reach of children.
- Do not use Nimbex after the expiry date shown on the pack after 'Exp'. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C - 8°C). Do not freeze.
- Store in the original package in order to protect from light.
- If diluted, store the infusion solution between 2°C and 8°C and use within 24 hours. Any unused infusion solution should be discarded 24 hours after it was prepared.
- Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicine that is no longer required. This will help protect the environment.

6 Contents of the pack and other information

What Nimbex contains

- The active substance is 2 mg/ml or 5 mg/ml cisatracurium (as besilate).
- The other ingredients are benzene sulfonic acid (32% w/v) and Water for Injections.

What Nimbex looks like and contents of the pack

Nimbex 2 mg/ml solution for injection/infusion comes:

- 2.5 ml clear glass ampoule in a box of 5 (each 2.5 ml ampoule contains 5 mg of cisatracurium)
- 5 ml clear glass ampoule in a box of 5 (each 5 ml ampoule contains 10 mg of cisatracurium)
- 10 ml clear glass ampoule in a box of 5 (each 10 ml ampoule contains 20 mg of cisatracurium)
- 25 ml clear glass ampoule in a box of 2 (each 25 ml ampoule contains 50 mg of cisatracurium)

Nimbex Forte 5 mg/ml solution for injection/infusion comes in a box containing one 30 ml clear glass vial. Each 30 ml vial contains 150 mg of cisatracurium.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder:

Aspen Pharma Trading Limited,
3016 Lake Drive,
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Manufacturer:

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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Nimbex 2 mg/ml solution for injection Nimbex Forte 5 mg/ml solution for injection
Reference number	PL 39699/0092

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