

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Nimbex 2 mg/ml solution for injection/infusion**

cisatracurium

**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. 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 of Nimbex (listed in section 6)
- if 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)
- 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.

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
- anticholinesterases used to treat Alzheimer's disease such as donepezil.

### **Pregnancy and breast-feeding**

An adverse impact of cisatracurium on the breastfed child cannot be excluded, however it is not expected if breastfeeding is restarted after the effects of the substance have worn off. Cisatracurium is quickly eliminated from the body. Women should abstain from breastfeeding for 3 hours after the treatment discontinuation.

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**

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. 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 and shock.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). 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 cisatracurium (*as besilate*).
- The other ingredients are benzene sulfonic acid (32% w/v) and water for injection.

**What Nimbex looks like and contents of the pack**

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

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)

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Manufacturing Authorisation Holder:

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.  
Tel: +353 1 6 308 400

Manufacturer:

GlaxoSmithKline Manufacturing S.p.A., Strada Asolana, 90 San Polo di Torille, Parma 43056, Italy.  
Aspen Pharma Ireland Limited, One George's Quay Plaza, Dublin 2, Ireland  
Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**Nimbex:** UK, Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain

**This leaflet was last revised in July 2021**

Detailed information on this medicine is available on the website of the Health Products Regulatory Authority (HPRA).

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### **Nimbex 2 mg/ml solution for injection/infusion**

cisatracurium

**The following information is intended for medical or healthcare professionals only. Please refer to the Summary of Product Characteristics (SPC) for full prescribing information.**

This product is for single use only. Use only clear and almost colourless up to slightly yellow/greenish yellow coloured solutions. The product should be visually inspected before use, and if the visual appearance has changed or if the container is damaged, the product must be discarded.

Diluted Nimbex is physically and chemically stable for at least 24 hours at 5°C and 25°C at concentrations between 0.1 and 2 mg/ml in the following infusion fluids, in either polyvinyl chloride or polypropylene containers.

Sodium Chloride (0.9% w/v) Intravenous Infusion.

Glucose (5% w/v) Intravenous Infusion.

Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion.

Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion.

However, since the product contains no anti-microbial preservative, dilution should be carried out immediately prior to use, or failing this be stored as directed under section 5 of the package leaflet.

Nimbex has been shown to be compatible with the following commonly used peri-operative drugs, when mixed in conditions simulating administration into a running intravenous infusion via a Y-site injection port: alfentanil hydrochloride, droperidol, fentanyl citrate, midazolam hydrochloride and sufentanil citrate. Where

other drugs are administered through the same indwelling needle or cannula as Nimbex, it is recommended that each drug be flushed through with an adequate volume of a suitable intravenous fluid, e.g. Sodium Chloride Intravenous Infusion (0.9% w/v).

As with other drugs administered intravenously, when a small vein is selected as the injection site, Nimbex should be flushed through the vein with a suitable intravenous fluid, e.g. Sodium Chloride Intravenous Infusion (0.9% w/v).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **Instructions to open the ampoule**

Ampoules are equipped with the OPC (One Point Cut) opening system and must be opened following the below instructions:

- Hold with the hand the bottom part of the ampoule as indicated in picture 1
- Put the other hand on the top of the ampoule positioning the thumb above the coloured point and press as indicated in picture 2



Picture 1

Picture 2

