PACKAGE LEAFLET: INFORMATION FOR THE USER

Novistig 0.5 mg/ml + 2.5 mg/ml solution for injection

Glycopyrronium bromide/Neostigmine metilsulfate

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 or pharmacist.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Novistig is and what it is used for

Novistig contains two active ingredients:
- Neostigmine metilsulfate which belongs to a group of medicines called cholinesterase inhibitors. It has the effect of reversing the action of certain muscle-relaxing drugs
- Glycopyrronium bromide which belongs to a group of medicines called anticholinergic drugs. Its purpose is to block some of the unwanted effects that may occur with neostigmine metilsulfate such as slowing the heart rate or excess production of saliva.

Glycopyrronium bromide and neostigmine metilsulfate Injection is used at the end of an operation to reverse the effects of some of the drugs used during surgery such as anaesthetics and muscle relaxants.

2. What you need to know before you are given Novistig

Do not use Novistig:

- if you are allergic to glycopyrronium bromide or neostigmine metilsulfate or any of the other ingredients of this medicine (listed in section 6)
- if you have a blockage in your stomach, intestine or urinary passages such as bladder or kidneys
- if you are also receiving suxamethonium, a muscle relaxant usually given during operations.

Make sure your doctor knows if you suffer from any of the above.

Warnings and precautions

Talk to your doctor <or nurse> before you are given Novistig
- if you suffer from asthma or attacks of wheezing
- if you suffer from glaucoma (increased pressure in the eye)
- if you have had a recent operation on the intestines (gut)
- if you suffer from increased body temperature (especially children)
- if you have high blood pressure
- if you suffer from cardiac arrhythmia (irregular heart beats) or slow heart rate
- if you suffer from heart failure or heart disease
- if you are under influence of anaesthetics like Cyclopropane or Halothane
- if you suffer from myasthenia gravis (leading to muscle weakness and fatigue)
- if you have an enlarged prostrate gland
- if you suffer from obstruction of the stomach (pyloric stenosis) or bowel causing vomiting, abdominal pain and swelling (paralytic ileus)
- if you have an overactive thyroid gland

- if you are suffering from epilepsy or Parkinsonism (a disorder in the brain causing muscle stiffness and shaking).

Tell your doctor if any of these apply to you.

Other medicines and Novistig

Tell your doctor if you are taking/using, have recently taken/used, or might take/use any other medicines

- medicines to treat depression (e.g. Tricyclic Antidepressant, MAOI's- Monoamine oxidase inhibitors)
- medicine used to treat mental illness (e.g. Clozapine)
- medicine used to relieve the pain (e.g Nefopam)
- amantadine which is used to treat Parkinson's disease or viral infection
- suxamethonium, a muscle relaxant usually given during operations.

Pregnancy, breast-feeding and fertility

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 using this medicine.

Driving and using machines

This medicine may cause your eyesight to become weak and this could interfere with your ability to drive or operate machinery safely.

Ask your doctor for advice before you drive or operate machinery.

Novistig contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml (per ampoule), that is to say essentially 'sodium-free'.

3. How to use Novistig

This medicine must only be administered by your doctor or nurse.

The recommended dose is:

For Adults and elderly patients: your doctor will inject 1 – 2 ml intravenously over a period of 10 to 30 seconds. Alternatively, your doctor will administer a specific dose based on your body weight (i.e. 0.02 ml/kg) over a period of 10-30 seconds.

Paediatric population: your doctor will administer a specific dose based on your body weight (i.e. 0.02ml/kg) over a period of 10 to 30 seconds. Alternatively, your doctor will dilute to 10 ml with water for injections and administer 1 ml per 5 kg bodyweight.

Your doctor will decide the correct dose for you depending on your circumstances. Your dose may be calculated according to your weight. The injection is usually given over a period of 10-30 seconds and may need to be repeated depending on your response.

If you have been given more Novistig than you should

This is unlikely because the dose will be administered by a health professional.

An overdose may cause changes in the speed of heart rate, increased production of saliva and difficulty in breathing. If you suspect you have been given too much, you should tell the doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor <or nurse>.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects to look out for:

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Contact a doctor right away if you notice any of the following symptoms - you may need urgent medical treatment:

Swelling of the face, lips or throat which makes it difficult to swallow or breathe, rash, itching, hives and dizziness. This could be a sign of an angioedema or a severe allergic reaction (frequency not known, cannot be estimated from the available data).

The following side effects have also been reported but their frequency is not known:

- dry mouth
- difficulty in passing stools (Constipation)
- slow heart rate (Bradycardia)
- an awareness of strong, thumping heart beats (Palpitation) or irregular heart beats
- reduced secretion in lung
- difficulty in passing urine
- increased sensitivity of the skin to light (Photophobia)
- dryness of the skin
- reddening of the skin (Flushing)
- confusion
- nausea (Feeling sick), vomiting (Being sick), dizziness
- eye disorder (Glaucoma)
- dilated pupils
- blurred vision
- increased secretions of stomach and inhibition/decreased sweating.

If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Novistig

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the ampoule and the outer carton. The expiry date refers to the last day of that month.
Do not freeze.
Use immediately after first opening. For single use only.
Novistig should not be administered if noticed that the solution is not clear and free from particles.
As this medicine is limited to hospital use the disposal is carried out directly by the hospital. Medicines should not be thrown away via wastewater. These measures will help to protect the environment.

6. Contents of the pack and other information

What Novistig contains

The active substances are Glycopyrronium Bromide and Neostigmine Metilsulfate.
Each glass ampoule contains 1 ml of solution, which contains the two active ingredients Glycopyrronium Bromide 0.5 mg and Neostigmine Metilsulfate 2.5 mg.
The other ingredients are Disodium phosphate dodecahydrate (E339), Citric acid anhydrous (E330), Sodium hydroxide (for pH adjustment) (E524) or Citric acid solution (for pH adjustment) in Water for injections.

What Novistig looks like and contents of the pack

This medicine is presented as a solution for injection. The solution for injection is a clear, colourless solution, practically free of visible particles.
It comes in Type I clear colourless glass 2 ml (filled to 1 ml) ampoule.
Box of 10 ampoules containing 1 ml of solution for injection.

Marketing Authorisation Holder and Manufacturer

Sintetica GmbH
Albersloher Weg, 11
48155 – Münster
Germany

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

Austria	Combistig® 0,5 mg/ml + 2,5 mg/ml Injektionslösung
Germany	Novistig® 0,5 mg/ml + 2,5 mg/ml Injektionslösung
Greece	Novistig®
Croatia	Novistig®
Hungary	Novistig® 0.5 mg/ml + 2.5 mg/ml oldatos injekció
Ireland	Novistig® 0.5 mg/ml + 2.5 mg/ml solution for injection
Netherlands	Novistig®
Poland	Novistig®
Slovenia	Novistig® 0,5 mg/2,5 mg v 1 ml raztopina za injiciranje

This leaflet was last revised in 08/2022.

The following information is intended for medical or healthcare professionals only:

The SmPC is added at the end of the printed PL as a tear-off section.