

Novistig

Solution for injection

Glycopyrronium bromide (glycopyrrolate) - Neostigmine methylsulfate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given Novistig.

This leaflet answers some common questions about Novistig. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au.

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

All medicines have risks and benefits. Your doctor has weighed the risks of giving you Novistig against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Novistig is used for

Novistig contains glycopyrronium bromide (glycopyrrolate) and neostigmine methylsulfate.

Neostigmine belongs to a group of medicines called cholinesterase inhibitors. It has the effect of reversing the action of certain muscle-relaxing medicines.

Novistig is used at the end of an operation to reverse the effects of some of the medicines used during

surgery such as anaesthetics and muscle relaxants.

Glycopyrronium bromide belongs to a group of medicines called anticholinergic medicines. Its purpose is to block some of the unwanted effects that may occur with neostigmine such as slowing the heart rate or excess production of saliva.

Ask your doctor if you have any questions about why it has been prescribed for you.

Novistig is only available with a doctor's prescription.

Novistig is not addictive.

Before you are given Novistig

Novistig is not suitable for everyone.

When you must not be given it

You must not be given Novistig:

- at the same time as you are also receiving suxamethonium, a muscle relaxant usually given during operations
- if you have blockage of the intestines or urinary tract.

Tell your doctor if you suffer from any of the above.

You must not be given Novistig if you are allergic to any medicine containing glycopyrronium bromide (glycopyrrolate), neostigmine methylsulfate or any of the ingredients listed at the end of this leaflet.

Novistig must not be used after the expiry date ('EXP') printed on the pack, or if the packaging is torn or shows signs of tampering. The solution must be clear before use.

If you are not sure whether you should be given Novistig, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- recent surgery involving the intestine or bladder
- other intestinal or bladder problems
- asthma
- glaucoma
- heart disease or other heart problems
- epilepsy
- low or high blood pressure
- Parkinson's disease
- stomach ulcer or bowel problems
- hiatus hernia
- kidney problems
- Addison's disease
- an overactive thyroid gland
- difficulty urinating, or enlarged prostate
- myasthenia gravis, a muscle weakness disorder
- nerve or brain disorder, brain damage, or Down's Syndrome.

It may not be safe for you to be given Novistig if you have any of these conditions.

Do not use this medicine if you are pregnant or intend to become pregnant.

The safety of the use of this medicine in women who are pregnant or may become pregnant has not been established. Novistig is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not breast-feed if you are using this medicine.

The active ingredient in Novistig passes into breast milk and there is a possibility that your baby may be affected.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Novistig.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are using Novistig.

Some medicines and Novistig may interfere with each other. These include:

- corticosteroids
- antibiotics
- lithium
- chloroquine, hydroxychloroquine, quinine
- medicine for heart problems including beta-blockers
- medicines to treat depression (e.g. tricyclic antidepressants, MAOI's)
- medicines used to treat mental illness (e.g. clozapine)
- medicines used to relieve pain (e.g. nefopam)

- amantadine, which is used to treat Parkinson's disease or viral infections
- sugammadex or suxamethonium, muscle relaxants usually given during operations.

The above medicines may be affected by Novistig, or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given Novistig.

How Novistig is given

How it will be given

Novistig will be given to you by injection by a doctor or a specially trained nurse.

How much will be given

Your doctor will know how much Novistig you should be given.

The need for more doses will depend on how well your body responds to the treatment. Your doctor will decide how many injections you need, and how often you should receive them.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

This depends on your condition and whether or not you are taking any other medicines.

If you receive the wrong dose, Novistig may not work as well and your problem may not improve.

While you are being given Novistig

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Novistig. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are being given this medicine.

Things to be careful of

Be careful if you are elderly or unwell.

Some people may experience side effects such as drowsiness, or blurred vision, which may increase the risk of a fall.

Be careful during warm weather and temperature, and/or with physical exercise after use of Novistig.

It may reduce your ability to sweat and can therefore cause overheating.

Be careful driving or operating machinery until you know how Novistig affects you.

It 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.

In case of overdose

If you are given too much

As Novistig is given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, symptoms of an overdose may include nausea, vomiting, muscle cramps, sweating, increased saliva and changes in heart rate.

Immediately tell your doctor or nurse if you think that you or anyone else may have been given too much Novistig.

They have information on how to recognise and treat an overdose.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Novistig.

Like all medicines, Novistig may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Tell your doctor or nurse if you notice any of the following and they worry you:

- fast, slow or irregular heart beat
- high blood pressure
- flushing
- sweating or unable to sweat
- feeling sick or vomiting
- dry mouth or increased saliva or mucous production
- dry and/or itchy skin
- constipation, diarrhoea
- difficulty urinating or involuntary urination or defecation
- impotence
- reduced milk supply in breastfeeding women
- blurred vision or other problems with your eyesight
- headache
- nervousness, drowsiness or restlessness
- dizziness, faintness or weakness
- unable to sleep, sleep disorder
- over-excitement in children
- confusion, especially in elderly people

- fever
- feeling bloated or stomach cramps
- loss or alteration of taste
- muscle weakness, muscle cramps or twitching
- increased secretion of tears from the eyes
- slurred speech
- inability to smile, swallow, speak, cough, track objects with eyes
- inability to perform a deep breath
- chest discomfort
- facial weakness, facial numbness.

These side effects are usually mild.

Rare side effects include: injection site reactions like itchy skin, swelling, pain.

Tell your doctor immediately if you notice any of the following:

- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- cold sweat, nausea, light-headedness, discomfort in the chest or other areas of the upper body, e.g. pain or discomfort in one or both arms, the back, neck, jaw or stomach.

These may be serious side effects.

You may need urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After being given Novistig

Storage

Novistig will be stored in the pharmacy or on the ward under the recommended storage conditions.

It must be kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Disposal

Any Novistig which has passed its expiry date, or is left in the container after use, will be disposed of in a safe manner by your doctor, nurse or pharmacist.

Product description

What it looks like

Novistig is a clear sterile solution for injection.

It is available in glass ampoules of 1 mL in size. Each carton contains 10 ampoules.

Ingredients

Active ingredients:

- glycopyrronium bromide (glycopyrrolate)
- neostigmine methylsulfate.

Inactive ingredients:

- dibasic sodium phosphate dodecahydrate
- citric acid
- sodium hydroxide
- water for injections.

Novistig does not contain lactose, sucrose, tartrazine or any other azo dyes. Preservative and sulfite free.

Sponsor details

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