

Neostigmine Methylsulfate Injection BP 2.5 mg in 1ml

Neostigmine Methylsulfate

- Read all of this leaflet carefully before you start using 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, please ask your doctor or your pharmacist.

What is in this leaflet

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

1. What Neostigmine Methylsulfate Injection is and what it is used for

Neostigmine injection belongs to a group of medicines used to:

- Treat abnormally tired and weak muscles (myasthenia gravis).
- · Reverse the effects of muscle relaxants.
- Improve movement in the small intestine.
- Reduce urine retention after surgical procedures.

2. What you need to know before you are given Neostigmine Methylsulfate Injection

Do not use Neostigmine Methylsulfate Injection if you:

- are allergic to neostigmine or any of the other ingredients in this medicine (listed in section 6).
- have an intestinal obstruction or cannot urinate.
- have peritonitis (an infection or inflammation of
- the outer layer of your stomach or intestines).

 have a condition where your bowel may no
- longer be functioning.you are receiving certain muscle relaxants (e.g.
- you are receiving certain muscle relaxants (e.g. Suxamethonium).

Warning and precautions

Talk to your doctor or nurse before being given the injection if you have:

- asthma
- epilepsy
- a slow pulse
- · any heart disease
- vagotonia (you may suffer from sweating, constipation and involuntary movements)
- · an overactive thyroid gland
- · a stomach ulcer
- Parkinson's Disease
- an anastomosis (an opening created by surgery, trauma, or disease) in your intestine

Other medicines and Neostigmine Methylsulfate Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important with the following medicines as they may interact with your Neostigmine Methylsulfate Injection:

 you are receiving antibiotics known as aminoglycosides.

Neostigmine Methylsulfate Injection contains sodium

This medicine contains 3.54 mg (0.15 mmol) sodium (main component of cooking/table salt) per 1 ml ampoule, that is to say essentially 'sodium-free'

Pregnancy or breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

You should not drive or use machinery if you are affected by the administration of Neostigmine Methylsulfate Injection.

3. How to use Neostigmine Methylsulfate Injection

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.

4. Possible side effects

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

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.

The following information is intended for healthcare professionals only: PREPARATION GUIDE:



Neostigmine Methylsulfate Injection BP 2.5 mg in 1ml

Please refer to the Summary of Product Characteristics for full prescribing and other information.

Therapeutic indications

Indications: Myasthenia Gravis, antagonist to non-depolarizing neuromuscular blockade, Paralytic Ileus, Post-operative Urinary Retention; Paroxysmal Supraventricular Tachycardia.

Administration

Neostigmine Methylsulfate may be administered by IV, IM or SC injection.

Incompatibilities

Neostigmine may be diluted with Water for Injections. Stability of the injection cannot be quaranteed once it has been diluted.



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:

You may (frequency not known, cannot be estimated from the available data):

- · feel or actually be sick
- · produce more saliva than usual
- produce more tears than usual
- suffer from bronchial spasm and increased bronchial secretion
- · suffer from diarrhoea and stomach cramps
- · have constricted (pin-point) pupils in your eye
- suffer from urinary incontinence (you pass urine when you do not mean to)
- suffer from excessive sweating
- have a slow pulse
- suffer from hypotension (blood pressure that is much lower than usual)
- · suffer from muscle spasms

If you experience any of the side effects listed this may mean that you have been given an overdose and you should tell a doctor immediately.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Neostigmine Methylsulfate Injection

Your injection will be stored at less than 25°C and protected from light. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection.

6. Contents of the pack and other information

What Neostigmine Methylsulfate Injection contains

The active ingredient is Neostigmine Methylsulfate. Each 1 ml of solution contains 2.5 mg neostigmine methylsulfate.

The other ingredients are Sodium Chloride, Sterile Water for Injections.

What Neostigmine Methylsulfate Injection looks like and contents of the pack

Neostigmine Methylsulfate Injection is a clear colourless solution in clear glass ampoules containing 2.5 mg neostigmine methylsulfate in 1 ml. 10 ampoules are supplied in each carton.

The marketing authorisation number of this medicine is: PL 01502/0023

Marketing Authorisation Holder

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Manufacturer

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For any information about this medicine, please contact the Marketing Authorisation Holder

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The following information is intended for healthcare professionals only: (Continued from overleaf)



Neostigmine Methylsulfate Injection BP 2.5 mg in 1ml

Shelf life

36 Months.

Special precautions for storage

Protect from light and store at less than 25°C.