



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

NEOSTIGMINE INJECTION

Neostigmine Methylsulphate 0.5mg/ml

Neostigmine Methylsulphate 2.5mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

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

1. WHAT NEOSTIGMINE INJECTION IS AND WHAT IT IS USED FOR

Neostigmine Injection belongs to a group of medicines called cholinesterase inhibitors. Neostigmine Injection is used:

- To reverse the effects of some muscle relaxants
- In a condition where muscles become abnormally tired and weak (myasthenia gravis) and it is not suitable to give the treatment by mouth
- To improve the movement of the small intestine
- To reduce the inability to urinate or to relieve the feeling of being bloated after an operation.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NEOSTIGMINE INJECTION

You must not be given Neostigmine:

- If you are allergic to Neostigmine or any of the other ingredients of this medicine. Tell your anaesthetist if this applies to you.

You should not be given Neostigmine Injection:

- If you are allergic to Neostigmine Methylsulfate or any of the other ingredients of this medicine
- If you have an obstruction in your stomach, intestine or cannot urinate
- If you have stomach pain, inflammation or infection of the outer layer of your stomach or intestines (peritonitis)
- If you are receiving Suxamethonium, a muscle relaxant usually given during operations.

Tell your doctor if any of these applies to you before you are given this medicine.



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Warnings and precautions

Talk to your doctor or nurse before Neostigmine Injection is given to you if:

- You suffer from asthma.
- You have a very slow heartbeat (less than 60 beats per minute) or you are suffering from heart disease which may cause heart failure, irregular heartbeats or low blood pressure
- You suffer from an overactive thyroid gland.
- You have a stomach ulcer.
- You are suffering from fits or a brain disorder causing shaking, rigidity and slowing of movements (Parkinson's disease)
- You are elderly
- You are allergic to neostigmine, as taking this medicine would cause a severe skin rash (cholinergic reaction).

Speak to your doctor if any of these applies to you before you are given this medicine. Neostigmine Injection may cause the heart to beat very slowly (less than 60 beats per minute). Your doctor will take measures to prevent this from happening.

Other medicines and Neostigmine Injection

Tell your doctor if you are taking, have recently taken or might take any other medicines including the following:

- Cyclopropane, Thiopental or Halothane anaesthetics
- Certain muscle relaxants such as Succinylcholine or Atropine
- Certain antibiotics known as Aminoglycosides such as Neomycin sulphate and Gentamicin
- Beta blockers e.g., Propranolol, Atenolol.

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 taking this medicine.

As with all drugs, Neostigmine Injection should only be used during pregnancy and breast-feeding when your doctor decides that the benefits to you are greater than any possible risk to the baby.

Driving and using machines

Neostigmine Injection may cause drowsiness and dizziness which could interfere with your ability to drive or to use machines. Do not drive or operate machinery whilst you are taking this medicine. When your Neostigmine Injection treatment has stopped, ask your doctor when it will be safe for you to drive or use machines.

3. HOW TO TAKE NEOSTIGMINE INJECTION

Neostigmine Injection is administered by injection into a vein, into the muscle or into the



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tissue just beneath the skin.

Your doctor will decide the correct dose for you, depending on your circumstances.

Your dose may be calculated according to your weight.

If you think you have been given more Neostigmine Injection than you should

This is unlikely because this medicine will be administered by a doctor. If you are concerned about the dose, discuss this with your doctor.

An overdose may cause slowing of your heartbeat, low blood pressure, increased production of saliva, muscle weakness and difficulty in breathing.

If you think you have missed a dose of Neostigmine Injection:

If you think that you have missed a dose, tell your doctor or nurse 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.

All medicines can cause allergic reactions although serious allergic reactions are very rare. Allergic reactions such as any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), a severe, potentially life-threatening allergic reaction (anaphylactic reaction) should be reported to a doctor immediately.

The other possible side effects are listed under headings of frequency, using the following categories:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data

The following side effects have also been reported:

Not known (frequency cannot be estimated from the available data)

- Heart attack (characterized by fainting, fatigue, blackouts, dizziness, chest pain, shortness of breath, weakness, and vomiting)
- Feeling sick or being sick, loss of appetite
- Stomach cramps or diarrhoea
- Decrease in heart rate or abnormal heart beats
- An increase in saliva production
- Drowsiness or dizziness.

If any of the side effects gets serious, or if you notice any side effect not listed in this



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leaflet, please tell your doctor or nurse.

Reporting of side effects

If you get any side effect, talk to your doctor or nurse. This includes any possible side effect not listed in this leaflet.

5. HOW TO STORE NEOSTIGMINE INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Neostigmine Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What NEOSTIGMINE INJECTION contains

Each ml of Neostigmine 0.5mg Injection contains 0.5mg of Neostigmine Methylsulphate.

Each ml of Neostigmine 2.5mg Injection contains 2.5mg of Neostigmine Methylsulphate.

What NEOSTIGMINE INJECTION looks like and contents of the pack

Clear transparent liquid in a 10x1ml Ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

Fidson Healthcare Plc,
17-21, Fidson Avenue
Sango-Ota, Ogun State,
Nigeria.
234-(0)8077008888
Customercare@fidson.com

	Prepared by	Approved by	
Signature			
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