

## **Package leaflet: Information for the user**

### **Neostigmine Metilsulfate 2.5mg/ml Solution for Injection** 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This product will be referred to as Neostigmine Injection from here on.

#### **What is in this leaflet**

1. What Neostigmine Injection is and what it is used for
2. What you need to know before you are given Neostigmine Injection
3. How Neostigmine Injection is given to you
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 in the small intestine
- to reduce the inability to pass water or to relieve the feeling of being bloated after an operation.

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

##### **You should not be given Neostigmine Injection:**

- if you are allergic to neostigmine metilsulfate or any of the other ingredients of this medicine (listed in section 6)
- 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 apply to you before you are given this medicine.

#### **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 heart beat (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 apply 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 avoid this happening.

### **Other medicines and Neostigmine Injection**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

- 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 Neostigmine Injection is given to you**

Neostigmine Injection is administered by injection into a vein, into the muscle or into the 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 heart beat, 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
- drowsiness or dizziness.

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

### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. 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](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Neostigmine Injection**

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 carton and ampoule label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

For single use only.

If only part used, discard the remaining solution. The product should be used immediately after opening.

Do not use if the ampoule is damaged or if the contents are discoloured or deteriorated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Neostigmine Injection contains**

- The active substance is neostigmine metilsulfate. Each 1ml contains 2.5mg neostigmine metilsulfate.
- The other ingredients are dilute sulphuric acid and water for injections.

### **What Neostigmine Injection looks like and contents of the pack**

Neostigmine Injection is a clear, colourless sterile solution for injection in 1ml amber glass ampoule.

Pack size: 10 x 1ml ampoules

**Marketing Authorisation Holder**

Mercury Pharmaceuticals (Ireland) Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

**Manufacturer**

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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