PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Neostigmine Methylsulphate 0,5 mg/1 ml (Ampoules) Fresenius

Neostigmine Methylsulphate 2,5 mg/1 ml (Ampoules) Fresenius

Solution for injection.

Neostigmine methylsulphate.

Sugar free.

Read all of this leaflet carefully before you are given Neostigmine Methylsulphate Fresenius

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

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

1. What Neostigmine Methylsulphate Fresenius is and what it is used for

Neostigmine methylsulphate belongs to a group of medicines known as cholinergic substances.

It works by improving the transmission of nerve impulses in muscles so that the muscles are better able to work.

Neostigmine Methylsulphate Fresenius is used to:

- improve movement in the small intestine;
- reduce urine retention after an operation;
- treat abnormally tired and weak muscles (myasthenia gravis);
- reverse the effects of muscle relaxants, using the 2,5 mg/1 ml injection.

2. What you need to know before you use Neostigmine Methylsulphate Fresenius

Neostigmine Methylsulphate Fresenius should not be administered to you:

- if you are hypersensitive (allergic) to neostigmine or any of the other ingredients of Neostigmine Methylsulphate Fresenius (see section 6);
- if you have an intestinal obstruction or cannot urinate;
- if you are receiving certain muscle relaxants (such as suxamethonium);
- if you have peritonitis (an infection or inflammation of the outer layer of your stomach or intestines);
- if you have diabetes (high blood sugar);
- if you have gangrene - a serious and potentially life-threatening condition that arises when a large mass of body tissue dies. This may occur after an injury or infection, or in people suffering from any chronic health problem affecting blood flow.

Warnings and precautions

Tell your doctor or health care provider before being given Neostigmine Methylsulphate Fresenius:

- if you have asthma;
- if you have recently undergone intestinal or bladder surgery;
- if you have a slow pulse, any heart rhythm problems or other heart disease;
- if you have epilepsy (“fits”);
- if you have hypotension (low blood pressure);
- if you have been diagnosed with an overactive thyroid gland;
- if you have Parkinson’s disease;
- if you have a stomach ulcer;
- if you have been diagnosed with vagotonia (you may have signs such as sweating, constipation and involuntary spastic movements with pain);
- if you have an anastomosis (an opening created by surgery, trauma or disease) in your intestine;
- if you are elderly;
- if you have any kidney disorder, including Addison’s disease (a disorder where your body does not produce enough hormones).

Other medicines and Neostigmine Methylsulphate Fresenius

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor or health care provider if you are currently using:

- antibiotics known as aminoglycosides, clindamycin or colistin (used to treat bacterial infection);
- general anaesthetics (used to induce a sleep-like state during surgical procedures);

- beta-blockers (used to treat high blood pressure, irregular heartbeat or chest pains);
- quinine (used to treat irregular heartbeat);
- chloroquine or hydroxychloroquine (used to treat malaria or rheumatoid arthritis);
- lithium (used to treat some types of depression);
- corticosteroids (medicines used to treat inflammatory conditions in your body such as asthma or arthritis);
- suxamethonium (used to induce muscle relaxation and short-term paralysis, usually to help with tracheal intubation).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before Neostigmine Methylsulphate Fresenius is administered to you.

You should not receive Neostigmine Methylsulphate Fresenius if you are pregnant or breastfeeding your baby.

Driving and using machines

Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how Neostigmine Methylsulphate Fresenius affects you.

3. How to use Neostigmine Methylsulphate Fresenius

You will not be expected to give yourself Neostigmine Methylsulphate Fresenius. It will be given to you by a person who is qualified to do so.

Your doctor will decide on the correct dosage for your condition and how and when the injection

will be given.

Neostigmine Methylsulphate Fresenius may be injected into a vein (intravenously), under the skin (subcutaneously) or into a muscle (intramuscularly).

If you have the impression that the effect of Neostigmine Methylsulphate Fresenius is too strong or too weak, tell your doctor or pharmacist.

If you receive more Neostigmine Methylsulphate Fresenius than you should

Since a health care provider will administer Neostigmine Methylsulphate Fresenius, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Neostigmine Methylsulphate Fresenius

Since a health care provider will administer Neostigmine Methylsulphate Fresenius, it is unlikely that a dose will be missed.

4. Possible side effects

Neostigmine Methylsulphate Fresenius can have side effects.

Not all side effects reported for Neostigmine Methylsulphate Fresenius are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Neostigmine Methylsulphate Fresenius, please consult your health care provider for advice.

If any of the following happens, stop receiving Neostigmine Methylsulphate Fresenius and tell your doctor immediately:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in

swallowing or breathing;

- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Neostigmine Methylsulphate Fresenius. You may need urgent medical attention or hospitalisation.

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

- changes in the way your heart beats (such as beating slower) which may lead to a heart attack (pressure, tightness, pain, or a squeezing or aching sensation in your chest or arms that may spread to your neck, jaw or back, indigestion, shortness of breath);
- difficulty breathing, wheezing or coughing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side-effects occurring with an unknown frequency:

- miosis (constriction of the pupil in your eyes);
- increased secretion of tears;
- low blood pressure;
- loss of body mass, nausea (feeling sick), vomiting (being sick), stomach cramps, diarrhoea, increased secretion of saliva;
- involuntary defecation;
- excessive sweating;
- muscle cramps, muscle twitching and weakness;
- urinary incontinence (passing urine involuntarily);

- increased secretion of mucus.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of Neostigmine Methylsulphate Fresenius.

5. How to store Neostigmine Methylsulphate Fresenius

- Store at or below 25 °C.
- Protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Neostigmine Methylsulphate Fresenius contains

Each 1 ml ampoule contains 0,5 mg Neostigmine methylsulphate.

Each 1 ml ampoule contains 2,5 mg Neostigmine methylsulphate.

The other ingredients are sulphuric acid (for pH-adjustment) and water for injection.

What Neostigmine Methylsulphate Fresenius looks like and contents of the pack

Clear, colourless solution in amber ampoules.

1 ml amber, type 1 glass OPC ampoules packed in blister trays and placed in an outer carton.

Boxes of 10 ampoules.

Holder of certificate of registration and manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten

Port Elizabeth 6020

South Africa

Tel.: 041 403 1600

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Registration numbers

Neostigmine Methylsulphate 0,5 mg/1 ml (Ampoules) Fresenius: C907 (Act 101/1965)

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