SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the drug product : Name of the medicinal product:**

MYOSTIGMIN

Neostigmine Injection BP

Strength:
2.5mg/ml

Pharmaceutical dosage form
Solution for Injection.

2. **Qualitative and quantitative composition :**

Each ml contains 2.5mg of Neostigmine Methylsulfate.

1 ampoule with 1 ml contains 2.5 mg Neostigmine Methylsulfate.

Excipient with known effect

This medicinal product contains approximately 3.54 mg sodium per each 1 ml ampoule – see section 4.4.

For a full list of excipients, see section 6.1.

3. **Pharmaceutical form :**

A clear, colourless solution.

4. **Clinical Particulars:**

4.1 Therapeutic indications:

Neostigmine Injection is indicated for:

- Reversal of the effects of nondepolarising neuromuscular blocking agents (e.g. tubocurarine, metocurine, gallamine or pancuronium) after Surgery.
- The prevention and treatment of postoperative distention and urinary retention after mechanical obstruction has been excluded.
- The symptomatic control of myasthenia gravis when oral therapy is impractical.

4.2 Dosage and method of administration:

Reversal of Effects of nondepolarizing neuromuscular blocking agents: When Neostigmine Injection is administered Intravenously, it is recommended that Atropine Sulfate (0.6 to 1.2 mg) also administered simultaneously using separate syringes. The usual dose is 0.5 mg to 2.5 mg Neostigmine Injection given by Slow Intravenous, Intramuscular or Subcutaneous Injection, repeated as required. Reversal of non-depolarising neuromuscular blockade by intravenous injection over 1minute, 50-70 micrograms/kg (Max.5mg) after or with glycopyrronium or atropine. It is recommended that the patient be well ventilated and a patent airway maintained until complete recovery. The drug should never be administered in the presence of high concentrations of Halothane or Cyclopropane. In Cardiac cases and

severely ill patients, it is advisable to titrate the exact dose of Neostigmine required, using a peripheral nerve stimulator
device parenteral drug products should be inspected visually for matter and discoloration prior to administration, whenever solution and container permit.

Treatment of postoperative distention - One ml of the 1:2000 solution (0.5mg) subcutaneously or intramuscularly, as required.

Treatment of urinary retention: 0.5 mg Neostigmine subcutaneously or intramuscularly. If urination does not occur within an hour, the patient should be catheterised. After the patient has voided, or the bladder has been emptied, continue the 0.5mg injection every three hours for atleast 5 injections.

Symptomatic control of myasthenia gravis: 0.5mg subcutaneously or intramuscularly. Subsequent doses should be based on the individual patients response.

4.3 Contraindications:

Neostigmine Injection B.P. is contraindicated in patients with known hypersensitivity to the drug. It is also contraindicated in patients with peritonitis or mechanical obstruction of the intestinal or urinary tract.

4.4 Precautions and Warnings: Warnings

Neostigmine Injection should be used with caution in patients with epilepsy, bronchial asthma, bradycardia, recent coronary occlusion, vagotonia, hyperthyroidism, cardiac arrhythmias or peptic ulcer. When large doses of neostigmine are administered, the prior or simultaneous injection of atropine sulfate may be advisable. Separate syringes should be used for Neostigmine and atropine because of the possibility of hypersensitivity in an occasional patient, atropine and antishock medication should always be readily available.

Precautions

GENERAL: It is important to differentiate between myasthenic crisis and cholinergic crisis caused by overdosage of Myostigmin Injection. Both conditions result in extreme muscle weakness but require radically different treatment.

4.5 Interaction with other drugs:

Neostigmine Metilsulfate does not antagonize, and may in fact prolong, the phase I block of depolarising muscle relaxants such as Suxamethonium or decamethonium. Certain antibiotics, such as neomycin, streptomycin, kanamycin should be used in the myasthenic patient only where definitely indicated, and then and careful adjustment should be made of the anticholinesterase dosage. Local and some general anaesthetics, antiarrhythmic agents and other drugs that interfere with neuromuscular transmission should be used cautiously.

Carcinogenesis, mutagenesis and impairment of fertility: There have been no studies with Neostigmine Metilsulfate which would permit an evaluation of its carcinogenic or mutagenic potential. Studies on the effect of Neostigmine Metilsulfate on fertility and reproduction have not been performed.

4.6 Pregnancy and Lactation:

Teratogenic Effects - Pregnancy category C.

There are no adequate or well controlled studies of Neostigmine in either laboratory animal or in pregnant women. It is not known whether Neostigmine Metilsulfate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

Non-teratogenic effects- Anticholinesterase drugs may cause teratogenic uterine irritability and induce premature labour when given I.V. to pregnant woman near term.

Nursing Mothers: It is not known whether Neostigmine Metilsulfate is excreted in human milk. Because of the potential for serious adverse reactions from Neostigmine Metilsulfate, a decision should be made whether to discontinue nursing or to discontinue the drug.

Paediatric use: Safety and effectiveness in children have not been established.

4.7 Effects on ability to drive and operate machine:

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

4.8 Adverse effects:

Side effects are generally due to an exaggeration of pharmacological effects of which salivation and fasciculation are the most common. Bowel cramps and diarrhea may also occur. The following adverse reactions have been reported following use of Neostigmine Metilsulfate.

Allergic: Allergic reactions and anaphylaxis.

Neurologic: Dizziness, convulsions, headache, miosis and visual changes. Cardiovascular: Cardiac arrhythmias, syncope and hypotension.
Respiratory: Increased oral, pharyngeal and bronchial secretions, respiratory depression, respiratory arrest and bronchospasm.

Dermatologic: Rash & Urticaria.

Gastrointestinal: Nausea, emesis, flatulence and increased peristalsis. Musculoskeletal: Muscular cramps and spasms.

Adverse effects of Neostigmine are chiefly those of exaggerated response to parasympathetic stimulation.

System Organ Class	Adverse reaction	Frequency
Immune system disorders	Hypersensitivity, angioedema, anaphylactic reaction.	Not known
Nervous system disorders	Cholinergic syndrome, especially at high doses. In patients with myasthenia gravis, cholinergic crisis may be difficult to distinguish from myasthenia crisis (see section 4.9).	Not known
Eye disorders	Miosis, lacrimation increased	Not known
Cardiac disorders	Bradycardia, decreased cardiac conduction, in severe cases possibly leading to heart block or cardiac arrest	Not known
Vascular disorders	Hypotension	Not known
Respiratory, thoracic or mediastinal disorders	Increased bronchial secretion, bronchospasm	Not known
Gastrointestinal disorders	Nausea, vomiting, diarrhoea, abdominal cramps, salivary hypersecretion. Increased intestinal motility may result in involuntary defecation.	Not known
Skin and subcutaneous tissue disorders	Hyperhidrosis	Not known
Musculoskeletal, connective tissue and bone disorders	Muscle spasms	Not known
Renal and urinary disorders	Urinary incontinence	Not known

4.8 Over dosage:

Overdosage of Neostigmine Injection can cause cholinergic crisis, which is characterized by increasing muscle weakness, and through involvement of the muscles of respiration, may result in death. Myasthenic crisis, accompanied by extreme muscle weakness and may be difficult to distinguish from cholinergic crisis on a symptomatic basis.

Treatment of the two conditions differs radically. Whereas the presence of myasthenic crisis requires more intensive anticholinesterase therapy, cholinergic crisis calls for the promt withdrawal of all drugs of this type.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

5. Pharmacological properties :

5.1 Pharmacodynamic properties :

Neostigmine inhibits the hydrolysis of acetylcholine by competing with acetyl choline for attachment to acetyl-cholinesterase at sites of cholinergic transmission. It enhances cholinergic action by facilitating the transmission of impulses across neuromuscular junctions. Neostigmine undergoes hydrolysis by cholinesterase and is also metabolised by microsomal enzymes in the liver. Protein binding to human serum albumin ranges from 15 to 25%.

5.2 Pharmacokinetic properties:

Following intramuscular administration, neostigmine is rapidly absorbed and eliminated. The clinical effects of Neostigmine usually begin within 20 to 30 minutes after intramuscular injection and last from 2.5 to 4 hours.

Following I.V. administration, plasma half-life ranges from 47 to 60 minutes have been reported with a mean half-life of 53 minutes.

5.3 Pre-clinical Safety Data:

Not applicable

6. Pharmaceutical particulars:

6.1 List of Excipients:

Sodium Acetate BP
Glacial Acetic Acid BP
Water for Injections BP (Bulk)

6.2 Incompatibilities:

None

6.3 Shelf – life:
36 Months

6.4 Special precautions for storage:
Store below 30°C., protected from light. Do not freeze.

6.5 Nature and contents of container:
1 ml flint ampoule with purple band snap off packed in a carton. Such 5 ampoules packed in one blister pack, such 2 blister pack packed in a carton along with leaflet

6.6 Special Precautions for Handling and Disposal:
Use as directed by a physician.

7. Marketing authorization holder:
M/s. NEON LABORATORIES LIMITED
140, Damji Shamji Industrial Complex,
28, Mahal Indl. Estate, Mahakali Caves Road, Andheri (East), Mumbai - 400 093

8. Marketing authorization number :
CTD 2443

9. Date of first authorization / Renewal of the authorisation:

2025, December 2025

10. Date of revision of the text:
27th March 2026

11. Dosimetry: -------

12. Instructions For The Preparation Of Radiopharmaceuticals: ------