PRESCRIBING INFORMATION

[Pr]Neostigmine Methylsulfate Injection, USP

0.5 mg/mL

Parasympathomimetic

JAMP Pharma Corporation
1310 rue Nobel
Boucherville, Québec
J4B 5H3, Canada

Date of Preparation: April 26, 2023

Submission Control Number: 257362

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Parasympathomimetic

PHARMACOLOGY

Neostigmine inhibits the destruction of acetylcholine by cholinesterase, thus permitting free transmission of nerve impulses across the neuromuscular junction. It also has a direct effect on voluntary muscle fibers and possibly on autonomic ganglion cells and neurons of the CNS.

After absorption or intravenous (IV) administration, 80% of a dose is excreted by the kidney in the unchanged (50%) and metabolized (30%) forms in 24 hours. The elimination half-life is approximately 51 to 91 minutes.

INDICATIONS

Prophylaxis and treatment of postoperative intestinal atony, urinary retention; in serious cases of myasthenia gravis: to neutralize effect of curare in surgical anesthesia and shock therapy.

CONTRAINDICATIONS

Bronchial asthma or mechanical obstruction of intestinal or urinary tract. Known hypersensitivity to Neostigmine.

PRECAUTIONS

When large doses are given, simultaneous administration of atropine sulfate may be advisable. Because of the possibility of hypersensitivity in an occasional patient, atropine should always be at hand, together with antishock medications. Hypotension and bradycardia may occur if the effect of gallamine or curare is antagonized by neostigmine.

ADVERSE REACTIONS

The untoward effects of neostigmine are most commonly related to overdosage and generally are of two varieties: muscarinic and nicotinic. Among the former group are nausea, vomiting, diarrhea, abdominal cramps, increased salivation, increased bronchial secretions, miosis, and diaphoresis. Muscarinic untoward effects can usually be counteracted by atropine. Nicotinic untoward effects are chiefly muscle cramps, fasciculation and weakness, which can be difficult to distinguish from exacerbation of underlying myasthenia gravis.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Symptoms: Muscarinic and nicotinic effects (see **ADVERSE REACTIONS**). Distinguish from myasthenic crisis with edrophonium chloride, if necessary.

Treatment: Control muscarinic effects with IV atropine, followed by intramuscular (IM) atropine every 2 to 4 hours. Assist ventilation and treat convulsions or shock if necessary.

For management of a suspected drug overdose, contact your regional poison control centre.

DOSAGE AND ADMINISTRATION

Intestinal atony, postoperative: Prophylaxis: 250 mcg subcutaneous (SC) or IM before or immediately after operation, repeated every 4 to 6 hours SC. Treatment: 500 mcg SC, IM (or possibly IV) repeated at intervals of 4 to 5 hours.

Urinary Retention: Prophylaxis: 250 mcg as for intestinal atony. Treatment: 500 mcg SC or IM and apply heat to the lower abdomen. If urination does not occur within one hour, the patient should be catheterized. After the patient has voided, continue the 500 mcg injections at 3-hour intervals for at least 5 additional injections.

Curare Antagonist (to neutralize the effect of curare in surgical anesthesia and shock therapy): 0.5 to 2 mg IV. Atropine sulfate 0.6 to 1.2 mg IV should also be given.

DOSAGE FORMS, COMPOSITION, AND PACKAGING

Neostigmine Methylsulfate Injection, USP is a clear, colourless solution. Each mL contains neostigmine methylsulfate 0.5 mg and the following non-medicinal ingredients: acetic acid for pH adjustment, phenol 4.5 mg as preservative, sodium acetate trihydrate 0.2 mg as a buffer and sodium hydroxide for pH adjustment and water for injection. Available in 10 mL clear glass vials (Multidose), 10 vials per carton.

STORAGE AND STABILITY

Store between 15- 30°C. Protect from light. Multi-dose. Discard 28 days after initial use.

Do not use product if mixture (solution) shows haziness, particulate matter, discolouration, or leakage.

REFERENCES

1) NEOSTIGMINE OMEGA (Neostigmine Methylsulfate Injection USP), Prescribing Information, Omega Laboratories Limited, Date of revision: November May 24, 2012.

If you want more information about Neostigmine Methylsulfate Injection, USP:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.jamppharma.com), or by calling at 1-866-399-9091.

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