PRESCRIBING INFORMATION

[Pr]NEOSTIGMINE OMEGA

(Neostigmine Methylsulfate Injection USP)

0.5 mg/mL
1 mg/mL
2.5 mg/mL

Parasympathomimetic

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(Neostigmine Methylsulfate Injection USP)

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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:
• Report online at www.healthcanada.gc.ca/medeffect
• Call toll-free to 1-866-234-2345
• Complete a Canada Vigilance Reporting Form and:
- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 immediately.

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

0.5 mg/mL: Each mL contains Neostigmine Methylsulfate 0.5 mg, Phenol 0.45%, Sodium Acetate, Acetic Acid and Sodium Hydroxide as a buffer to adjust the pH and Water for Injection. Available in multidose vials of 1 mL and 10 mL, boxes of 10.

1 mg/mL: Each mL contains Neostigmine Methylsulfate 1 mg, Phenol 0.45%, Sodium Acetate, Acetic Acid and Sodium Hydroxide as a buffer to adjust the pH and Water for Injection. Available in multidose vials of 10 mL, boxes of 10.

2.5 mg/mL: Each mL contains Neostigmine Methylsulfate 2.5 mg, Phenol 0.45%, Sodium Acetate, Acetic Acid and Sodium Hydroxide as a buffer to adjust the pH and Water for Injection. Available in multidose vials of 5 mL, boxes of 10.

STORAGE AND STABILITY

Store between 15 and 30°C. Protect from light. Multiple use. Discard 28 days after initial use.

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

REFERENCES

1) Neostigmine Methylsulfate Injection USP Prescribing Information, Sandoz Canada Inc., Date of revision: November 12, 2007.