Only for the use of Medical Professionals

Stignal®

Neostigmine Methylsulfate

Description

Stignal® is a preparation of Neostigmine. Neostigmine is an antcholinesterase agent which inhibits reversibility the hydrolysis of acetycholine by competing with acetylcholine for attachment to acetylcholinesterase. As a result, acetylcholine accumulates at cholinergic synapses and its effects are prolonged and exaggerated.

Neostigmine is therefore capable of producing a generalised cholinergic response, including meiosis, increased tonus of intestinal and skeletal musculature, constriction of bronchi and ureters, bradycardia and stimulation of salivary and sweat glands. In addition Neostigmine has a direct cholinomimetic effect on skeletal muscle and to a lesser extent to increase the activity of smooth muscle.

Indications

Stignal® Injection is indicated for:

- Reversal of the effects of nondepolarising neuromuscular blocking agents after surgery.
- Prophylaxis and treatment of post-operative urinary retention.
- Symptomatic treatment of myasthenia gravis.

Dosage and administration

Reversal of effects of nondepolarizing neuromuscular blocking agents

The usual dose is 0.5 to 2 mg neostigmine methylsulfate given by slow IV injection, repeated as required. Only in exceptional cases should the total dose of neostigmine methylsulfate exceed 5 mg. When neostigmine methylsulfate is administered IV, it is recommended that atropine sulfate (0.6 to 1.2 mg) also be given IV using separate syringes.

Prevention of postoperative distention and urinary retention

1 ml of the 1:4000 solution (0.25 mg) IM or SCas soon as possible after operation; repeat every 4 to 6 hours for 2 or 3 days.

Treatment of postoperative distention

1 ml of the 1:2000 solutions (0.5 mg) IM or SC, as required.

Treatment of urinary retention

1 ml of the 1:2000 solution (0.5 mg) IM or SC. If urination does not occur within an hour, the patient should be catheterized. After the patient has voided, or the bladder has been emptied, continue the 0.5 mg injections every 3 hours for at least 5 injections.

Symptomatic control of myasthenia gravis

1 ml of the 1:2000 solution (0.5 mg) IM or SC. Subsequent doses should be based on the individual patients' response.

Side effects:

Salivation, fasciculation are common. Bowel cramps, diarrhea. Dizziness, convulsions, loss of consciousness, drowsiness, headache, dysarthria, miosis visual changes, bradycardia, and tachycardia may also occur.

Precautions

Asthma, bradycardia, recent MI, epilepsy, hypotension, parkinsonism, vagoyonia, peptic ulceration. Atropine or other antidote to muscarinic effects may be necessary (Particularly when neostimine is given by injection). But it should not be given routinely as it may mask sign of overdose.

Warnings

Neostigmine 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 Methylsulfate Injection are administered, the prior or simultaneous injection of atropine sulfate may be advisable. Separate syringes should be used for the neostigmine and atropine. Because of the possibility of hypersensitivity in an occasional patient, atropine and antishock medication should always be readily available.

Use in pregnancy & lactation:

There are no adequate or well-controlled studies of neostigmine methylsulfate in either laboratory animals or in pregnant women. Neostigmine methylsulfate should be given to a pregnant woman only if clearly needed.

It is not known whether neostigmine methylsulfate is excreted in human milk. Neostigmine should be given to lactating mothers only when attending physician decides that benefits outweighs the risks.

Pediatric Use

Safety and effectiveness in children have not been established.

Contraindications

Neostigmine 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.

Drug Interactions

Neostigmine does not antagonize, and may in fact prolong, the phase I block of depolarizing muscle relaxants such as succinylcholine or decamethonium. Certain antibiotics, especially neomycin, streptomycin and kanamycin, have a mild but definite nondepolarizing blocking action

which may accentuate neuromuscular block. These antibiotics should be used in the myasthenic patient only when definitely indicated, and then careful adjustment should be made of the anticholinesterase dosage. Local and some general anesthetics, antiarrhythmic agents and other drugs that interfere with neuromuscular transmission should be used cautiously.

Overdose

Overdosage of neostigmine can cause cholinergic crisis, which is characterized by increasing muscle weakness, and through involvement of the muscles of respiration. Myasthenic crisis, due to an increase in the severity of the disease, is also accompanied by extreme muscle weakness and may be difficult to distinguish from cholingeric crisis on a symptomatic basis. Myasthenic crisis requires more intensive anticholinesterase therapy, cholinergic crisis calls for the prompt withdrawal of all drugs of this type. The immediate use of atropine in cholinergic crisis is also recommended.

Atropine may also be used to abolish or minimize gastrointestinal side effects or other muscarinic reactions.

Pharmaceutical Precautions

Store in acool and dry place. Protect from light.

Presentation

Stignal® 0.5mg/ml Injection: Each ampoule contains Neostigmine Methylsulfate USP 0.5 mg. Each ampoule contains Neostigmine Methlisulfate BP 0.5mg

Packaging quantities

Stignal® 0.5mg/ml Injection: carton of 5 ampoules

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