PRESCRIBING INFORMATION

Neo-Pyrolate® Injection IV

(Glycopyrrolate+Neostigmine Methyl Sulphate)

نیوٴ-پائرولیٹ انجکشن آئی وی

COMPOSITION:
Each 1ml ampoule contains:
Glycopyrrolate USP - - - - - - - - - - -0.5 mg
Neostigmine Methyl Sulphate BP- - 2.5 mg
Mfg. Specs. Brookes

DESCRIPTION:
Glycopyrrolate is an anti-cholinergic drug, which is a synthetic quaternary ammonium compound. It inhibits the muscarinic actions of acetylcholine; which results in reduction of gastrointestinal & urinary tract motility. It also inhibits salivary as well as bronchial secretions. Due to its highly polar quaternary ammonium group, it does not cross the blood brain barrier in contrast with atropine sulphate or scopolamine hydrobromide, which are non-polar tertiary amines and can cross blood brain barrier.

Neostigmine belongs to "Reversible" Carbamate inhibitors group. These drugs inhibit or inactivate acetyl cholinesterase.They cause acetylcholine to accumulate at cholinergic receptors and as a result causes excessive stimulation of cholinergic receptors throughout the central and peripheral nervous system.

Acetylcholine accumulation causes bradycardia, vasodilation and hypotension. It increases oropharyngeal and bronchial gland secretions, along with that due to smooth muscles contraction it may cause bronchoconstriction.

Neostigmine is routinely used during anaesthesia to reverse the action of non-depolarizing neuromuscular blocking agents.

With intravenous injection, the onset of action of Glycopyrrolate is generally evident within one minute. The vagal blocking effect persists for 2-3 hours while the anti-sialogogue effect persists for 7 hours (period longer than that of atropine)

After I.V. injection Neostigmine absorbs quickly, the distribution half life varies between 1 to 3.5 minutes while elimination half life ranges from 15 to 80 minutes.The major route of elimination is urinary pathway through which 80% of the drug is eliminated.

INDICATIONS:
Reversal of residual non-depolarising (competitive) neuromuscular block.

DOSAGE AND ADMINISTRATION:
Adults and older patients:
1-2 ml intravenously over a period of 10-30 seconds (equivalent to Neostigmine Methyl Sulphate 2.5 mg with Glycopyrrolate 0.5 mg to Neostigmine Methyl Sulphate 5 mg with Glycopyrrolate 1 mg). Alternatively 0.02 ml/kg intravenously over a period of 10-30 seconds may be used (equivalent to Neostigmine Methyl Sulphate 50 micrograms/kg with Glycopyrrolate 10 micrograms/kg).

Children:
0.02 ml/kg intravenously over a period of 10-30 seconds (equivalent to Neostigmine Methyl Sulphate 50 micrograms/kg (0.05 mg/kg) with Glycopyrrolate 10 micrograms/kg (0.01 mg/kg). Alternatively dilute to 10 ml with water for injection, or sodium chloride injection 0.9% w/v and administer 1ml per 5 kg bodyweight.

These doses may be repeated if adequate reversal of neuromuscular blockade is not achieved. Total doses in excess of 2ml are not recommended as this dose of Neostigmine may produce depolarising neuromuscular block.

SIDE EFFECTS:
The Glycopyrrolate component of Neo-Pyrolate Injection can give rise to dry mouth, difficulty in micturition, cardiac dysrhythmias, disturbances of visual accommodation and inhibition of sweating, headache, drowsiness, weakness, nausea and vomiting. The Neostigmine component of Neo-Pyrolate Injection can give rise to bradycardia, increased oropharyngeal secretions, cardiac dysrhythmias and increased gastrointestinal activity. If severe Neostigmine induced muscarinic side effects occur (bradycardia, increased oropharyngeal secretions, decreased cardiac conduction rate,

bronchospasm or Increased Gastro-intestinal activity etc), these may be treated by the intravenous administration of Neo-Pyrolate Injection (Glycopyrrolate) 200-600 micrograms (0.2-0.6 mg).

CONTRAINDICATIONS:
Neo-Pyrolate Injection should not be given to patients with known hypersensitivity to either of the two active ingredients.
Neo-Pyrolate Injection should not be given to patients with mechanical obstruction of the gastrointestinal or urinary tracts.
Neo-Pyrolate Injection should not be given in conjunction with suxamethonium as Neostigmine potentiates the depolarising myoneural blocking effects of this agent.

CAUTIONS:
Administer with caution to patients with bronchospasm, severe bradycardia or glaucoma. Administration of anticholinesterase agents to patients with intestinal anastomoses may produce rupture of the anastomosis or leakage of intestinal contents.
Although Neo-Pyrolate has been shown to have less impact on the cardiovascular system than atropine with Neostigmine Methyl Sulphate.
Use with caution in patients with epilepsy or parkinsonism.
This product should be used cautiously in pyrexial patients due to inhibition of sweating.
Do not mix Neo-Pyrolate Injection with any other preparation.

USE IN PREGNANCY & LACTATION:
Although reproduction studies in rats and rabbits revealed no teratogenic effects from Glycopyrrolate, safety in human pregnancy and lactation has not been established. The significance of this for man is not clear. The safety of Neostigmine Methyl Sulphate in pregnancy and lactation has not been established.

TREATMENT OF OVERDOSAGE:
The treatment of overdosage depends upon whether signs of anticholinesterase or anticholinergic overdosage are the predominant presenting features. Signs of Neostigmine overdosage (bradycardia, increased oropharyngeal secretions, bronchospasm etc), may be treated by the administration of Pyrolate Injection (Glycopyrrolate 200-600 micrograms) (0.2-0.6 mg).
In severe cases, respiratory depression may occur and artificial ventilation may be necessary in such patients. Signs of Glycopyrrolate overdosage (tachycardia, ventricular irritability etc) may be treated by the administration of Neostigmine Methyl Sulphate (Neo-Choline) 1000 micrograms (1.0 mg) for each 1000 micrograms (1.0 mg) of Glycopyrrolate known to have been administered. As Glycopyrrolate is a quaternary ammonium agent, symptoms of overdosage are peripheral rather than central in nature; centrally acting anticholinesterase drugs such as physostigmine are therefore unnecessary to treat Glycopyrrolate overdosage.

STORAGE:
Store at temperature 15 to 30°C away from light.

PRESENTATION:
Neo-Pyrolate Injection I.V.
Pack of 10 x 1 ml ampoules

خوراک اور طریقہ استعمال :

بالغ مریض :

2-1 ملی لیٹر برائے وریدی انجکشن 30-10 سیکنڈ میں دیں۔

یا 0.02 ملی لیٹر/کلوگرام برائے وریدی انجکشن 30-10 سیکنڈ میں استعمال کریں۔

بچے :

0.02 ملی لیٹر/کلوگرام برائے وریدی انجکشن 30-10 سیکنڈ میں دیں۔

واٹر فار انجکشن یا سوڈیم کلورائیڈ انجکشن 0.9% کے ساتھ 10 ملی لیٹر تک محلول بنائیں اور 1 ملی لیٹر/کلوگرام وزن کے مطابق استعمال کریں

مطلوبہ نتائج نہ ملنے کی صورت میں یہ خوراک دوبارہ بھی دی جاسکتی ہے جبکہ مجموعی خوراک 2 ملی لیٹر سے تجاوز کرنے کی ممانعت ہے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیے

brookes

Manufactured by:

Brookes Pharma Private Limited
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Karachi 74900 Pakistan.