

PRESCRIBING INFORMATION

Pyrolate[®] Injection IV
(Glycopyrrolate Injection USP)

پائرولیٹ انجکشن آئی وی

COMPOSITION:

Each 1ml ampoule contains:
Glycopyrrolate USP 0.2 mg

DESCRIPTION:

Pyrolate (Glycopyrrolate Injection USP) is an anti-cholinergic drug which has been used in the treatment of peptic ulcer for a number of years and has recently been introduced into anaesthetic practice. It is a synthetic quaternary ammonium compound.

PHARMACOLOGY:

The following pharmacological effects are observed:

Pyrolate (Glycopyrrolate Injection USP) inhibits the muscarinic actions of acetyl choline. Depending on the dose, Pyrolate (Glycopyrrolate Injection USP) may reduce the motility and secretory activity of the gastrointestinal system, the tone of the ureter and urinary bladder. It also has a slight relaxant action on the bile duct and gallbladder.

In general, smaller doses of anti-cholinergics inhibit salivary and bronchial secretions, sweating and can cause dilatation of the pupil and increase in heart rate. Large doses are required to decrease motility of the gastrointestinal and urinary tracts and to inhibit the gastric acid secretion.

Anti-spasmodic effect on gastrointestinal tract is due to the direct action on smooth muscle.

Anti-dysmenorrhoeal effect is due to spasmolytic action on the uterine muscles. The highly polar quaternary ammonium group of glycopyrrolate limits its passage across lipid membranes, such as the blood brain barrier, as compared to atropine sulphate and scopolamine hydrobromide, which are non-polar tertiary amines and can cross blood-brain barrier. Peak effects occur approximately 30-45 minutes after intramuscular administration. The vagal blocking effect persists for 2-3 hours and the anti-sialogogue effect persists for 7 hours (period longer than that for atropine) With intravenous injection, the onset of action is generally evident within one minute.

INDICATIONS:

a) Anti-Muscarinic

1 Pyrolate (Glycopyrrolate Injection USP) is indicated for use as a pre-operative, anti-muscarinic drug to reduce salivary, tracheo-bronchial, and pharyngeal secretions.

1 To reduce the volume of free gastric acid and to raise pH of gastric contents above 2.5.

1 It also blocks cardiac vagal inhibitory reflexes during induction and intubation.

b) Anti-Arhythmic

Pyrolate (Glycopyrrolate Injection USP) may be used intra-operatively to counteract drug induced or vagal traction reflexes with associated arrhythmias.

c) Reversal of Neuromuscular Blockade

Pyrolate (Glycopyrrolate Injection USP) is indicated to reverse the neuromuscular block produced by non-depolarizing neuromuscular blocking agents, "in combination with" Neo-choline (Neostigmine) and pyridostigmine.

DOSAGE AND ADMINISTRATION:

Pyrolate (Glycopyrrolate Injection USP) may be administered intramuscularly or intravenously without dilution for the following:

a) Pre-Anaesthetic Medication

Prophylaxis of excessive salivation and respiratory tract secretions.

Adults:

4.4µg (0.0044 mg) per kg of body weight, one-half to one hour before induction of anaesthesia or at the time when the pre-anaesthetic narcotic or sedative are administered.

Children:

Intramuscular 4.4 to 8.8µg (0.0044 to 0.0088mg) per kg of body weight, one-half to one hour before induction of anaesthesia.

Infants:

1 Month to 2 years may require upto 0.009ml/kg dose

b) Intraoperative Medication

Counteract arrhythmias during surgery.

Adults:

Intravenous 100µg (0.1 mg), the dosage being repeated, if necessary at two to three minutes interval.

Children:

Intravenous 4.4µg (0.0044mg) per kg of body weight upto a maximum of 100µg (0.1mg), the dosage being repeated, if necessary, at two to three minutes intervals.

c) Reversal of Neuromuscular Block (Non-Depolarizing Type)

Adults:

Intravenous 200µg (0.2 mg), for each 1mg of neostigmine or 5 mg of pyridostigmine given simultaneously.

Note: In old age patients, the dose to be adjusted accordingly.

Children:

Intravenous 200µg (0.2 mg) for each, 1 mg of neostigmine or 5mg pyridostigmine given simultaneously.

SIDE EFFECTS:

Anti-cholinergics produce certain side effects most of which are extension of their pharmacological actions; they include: dry mouth, urinary retention, blurred vision, tachycardia, decreased sweating, loss of taste, headache, drowsiness, weakness, nausea, vomiting, suppression of lactation, constipation, allergic reactions and some degree of mental confusion or excitement.

CONTRAINDICATIONS:

- 1 Known hypersensitivity to glycopyrrolate
- 1 Due to its benzyl alcohol content, Pyrolate should not be used in newborn or children less than 1 month of age.
- 1 Concurrent glaucoma.
- 1 Obstructive diseases of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis)
- 1 Paralytic ileus, intestinal atony.
- 1 Un-stable cardiovascular status in acute haemorrhage.
- 1 Severe ulcerative colitis.
- 1 Myasthenia gravis.

CAUTIONS:

Investigate any tachycardia since an increase in heart rate may occur. Use with caution in patients with coronary artery disease, congestive heart failure, hypertension and hyperthyroidism.

STORAGE:

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

PRESENTATION:

Pyrolate (Glycopyrrolate Injection USP) is available in the Box of 10 x 1 ml ampoules.

مقدار اور طریقہ استعمال:

پائرولیٹ (گلیکوپیرولیت) مندرجہ ذیل حالتوں میں براہ راست عضلاتی (انسٹراسکلر) یا برائے ورید (انسٹراوینس) کو بغیر آمیزش کے لگایا جاسکتا ہے۔

بے ہوشی سے قبل خوراک: سانس کی نالی کی رطوبت اور منہ کے لعاب کی زیادتی کو کم کرنے کے لیے۔

بالغ: 4.4 ماگروگرام (0.0044 ملیگرام) فی کلگرام جسمانی وزن کے حساب سے، آدھے گھنٹے سے ایک گھنٹے بے ہوشی سے قبل یا اس وقت جب بے ہوشی سے قبل نشہ اور یا خواب آور اور ہیپتو ڈی جاکس۔

بچے: برائے عضلاتی انجکشن: 4.4 تا 8.8 ماگروگرام (0.0044 سے 0.0088 ملیگرام) فی کلگرام جسمانی وزن کے حساب سے، بے ہوشی گھنٹے آدھے سے ایک گھنٹے قبل۔

دورانِ جراحی مقدار:

بالغ: برائے ورید 100 ماگروگرام (0.1 ملیگرام) اور ضرورت پڑنے کی صورت میں مقدار کو دو سے تین منٹ کے وقفے سے دہرایا جاسکتا ہے۔

بچے: برائے ورید 4.4 ماگروگرام (0.0044 ملیگرام) فی کلگرام جسمانی وزن کے حساب سے، مقدار کی حد 100 ماگروگرام (0.1 ملیگرام) تک ہے اور ضرورت کی صورت میں دو یا تین منٹ کے وقفے سے مقدار کو دہرایا جاسکتا ہے۔

نیوروسکلر بلاک (نان ڈی پولارائزنگ قسم) کے اثرات کو ذائل کرنے کے لیے:

بالغ: برائے ورید 200 ماگروگرام (0.2 ملیگرام) ہر 1 ملیگرام نیواگلگین کے لیے یا 5 ملیگرام پائروڈونگلگین کے بیک وقت استعمال پر۔

نوٹ: ضعیف مریضوں کے لیے خوراک کی مقدار کو متب کیا جاسکتا ہے۔

بچے: ایک مہینے سے 12 سال تک

برائے ورید 200 ماگروگرام (0.2 ملیگرام) ہر 1 ملیگرام نیواگلگین یا 5 ملیگرام پائروڈونگلگین کے بیک وقت استعمال پر۔

اسٹوریج:

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

brookes

Manufactured by:

Brookes Pharma Private Limited
58 - 59 Sector 15 Korangi Industrial Area
Karachi 74900 Pakistan.

