Prescription only medicine

GLYCOPYRRONIUM BROMIDE SOLUTION FOR INJECTION 200 mcg/mL (1 mL & 3 mL)

(For IM/IV Use)

Composition

Each mL contains:

Glycopyrronium Bromide Ph. Eur. 200 mcg

Water for Injection Ph. Eur. q.s.

Presentation

Clear, colorless sterile solution.

Pharmaceutical form

Solution for injection.

Indication

1.To protect against the peripheral muscarinic actions of anticholinesterases such as neostigmine and pyridostigmine, used to reverse residual neuromuscular blockade produced by non-depolarising muscle relaxants.

2. As a pre-operative antimuscarinic agent to reduce salivary tracheobronchial and pharyngeal secretions and to reduce the acidity of the gastric contents.

3. As a pre-operative or intra-operative antimuscarinic to attenuate or prevent intra-operative bradycardia associated with the use of suxamethonium or due to cardiac vagal reflexes.

Recommended Dosage

Premedication or Intraoperative use

Adults: For premedication, the usual dose is 200 micrograms (0.2 mg) intravenously or intramuscularly, or 4 to 5 micrograms/kg (0.004 – 0.005 mg/kg), to a maximum of 400 micrograms (0.4 mg). During the operation, this dose may be given intravenously and may be repeated if necessary.

Children: For premedication, the recommended dose is 4 to 8 micrograms/kg (0.004 – 0.008 mg/kg) intramuscularly or intravenously to a maximum of 200 micrograms (0.2 mg). During the operation, this dose may be given intravenously and may be repeated if necessary.

Reversal of nondepolarising neuromuscular blockade

Adults: The usual dose is 200 micrograms (0.2 mg) intravenously per 1,000 micrograms (1 mg) of neostigmine or 5,000 micrograms (5 mg) of pyridostigmine. Alternatively, a dose of 10 to 15 micrograms/kg (0.01 – 0.015 mg/kg) intravenously per 50 micrograms/kg (0.05 mg/kg) of neostigmine. The drugs may be administered simultaneously by i.v. injection or mixed in the same syringe in order to minimize the appearance of cardiac side effects.

Children: 10 micrograms/kg (0.01 mg/kg) intravenously per 50 micrograms/kg (0.05mg/kg), neostigmine or equivalent dose of pyridostigmine.

Contraindication

Glycopyrronium bromide injection is contraindicated to patients with hypersensitivity to the active ingredient.

It may be contraindicated in patients with concurrent glaucoma, obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy), obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.), paralytic ileus, intestinal atony of the elderly or debilitated patient, unstable cardiovascular status in acute haemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis and myasthenia gravis.

Warning and Precautions

Glycopyrronium bromide injection should be used with caution in patients with coronary artery disease, congestive heart failure, hypertension, hyperthyroidism/thyrotoxicosis or in patients with cardiac arrhythmias.

Glycopyrronium bromide should be used with great caution in patients with glaucoma or asthma.

This product should be used very cautiously in pyrexial patients due to inhibition of sweating.

Large doses of quaternary ammonium anticholinergic compounds have been shown to block end plate nicotinic receptors. This should be borne in mind when considering use in patients with myasthenia gravis.

Diarrhoea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. Use of glycopyrronium bromide in such instance would be inappropriate and possibly harmful.

Any tachycardia should be investigated before giving glycopyrronium bromide, since an increase in the heart rate may occur. In managing ulcer patients, use glycopyrronium bromide

with caution in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease, ulcerative colitis or hiatal hernia, since anticholinergic drugs may aggravate these conditions.

Glycopyrronium bromide may produce drowsiness or blurred vision. Patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug.

Use in Children

Safety and effectiveness in children below the age of 12 years have not been established for the management of peptic ulcer.

Interaction with Other Medicaments

Administration of anticholinergic agents such as glycopyrronium bromide during inhalation anaesthesia can give rise to ventricular arrhythmias.

Pregnancy and Lactation

Glycopyrronium bromide should not be used during pregnancy unless considered essential by the physician. It is not known if the drug is excreted in human milk and caution should be exercised when glycopyrronium bromide is administered to a nursing woman.

Effects on Ability to Drive and Use Machine

Glycopyrronium bromide has moderate influence on the ability to drive and use machines. However, systemic administration of antimuscarinics may cause blurred vision, dizziness and other effects that may impair a patient's ability to perform skilled tasks such as driving. These activities should not be undertaken until any disturbance of visual accommodation or balance has resolved. Do not operate or drive heavy machinery unless the drug has been shown not to interfere with mental or physical ability.

Side Effects

The side effects of glycopyrronium bromide are mostly anticholinergic in nature, e.g. dry mouth, visual disturbances/blurred vision due to mydriasis, difficulty in micturition and urinary retention. Others include increased ocular tension, tachycardia, palpitation, decreased sweating, nausea, vomiting, drowsiness, insomnia, dizziness, weakness, nervousness, headache, loss of taste, impotence, suppression of lactation, constipation, bloated feeling, severe allergic reaction or drug idiosyncrasies including anaphylaxis, urticaria and other dermal

manifestations, some degree of mental confusion and/or excitement especially in elderly patients.

Symptoms & Treatment of Overdose

Symptoms of overdosage with glycopyrronium bromide are peripheral rather than central in nature, due to its poor penetration of the blood brain barrier. To counteract the peripheral anticholinergic effects, a quaternary ammonium anticholinesterase such as neostigmine methylsulphate may be given in a dose of 1,000 micrograms (1 mg) for each 1,000 micrograms (1mg) of glycopyrronium bromide known to have been administered by the parenteral route.

In an unlikely event that CNS symptoms (excitement, convulsions etc) occur, physostigmine (which crosses the blood-brain barrier) should be used. Physostigmine 0.5mg to 2mg should be slowly administered intravenously and repeated as necessary up to a total of 5mg in adults. Proportionately smaller doses should be used for children.

Fever should be treated symptomatically. In the event of a curare-like effect on respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns.

Properties

Pharmacodynamics

Pharmacotherapeutic group: Quaternary ammonium antimuscarinic

ATC Code: A03AB02

Glycopyrronium bromide is an anticholinergic (antimuscarinic) agent. It inhibits the action of acetylcholine on structures innervated by postganglionic cholinergic nerves and on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These peripheral cholinergic receptors are present in the autonomic effector cells of smooth muscle, cardiac muscle, the sinoatrial node, the atrioventricular node, exocrine glands, and to a limited degree, in the autonomic ganglia. Thus it diminishes the volume and free acidity of gastric secretions and controls excessive pharyngeal, tracheal, and bronchial secretions. Glycopyrronium bromide also antagonises muscarinic symptoms induced by cholinergic drugs such as the anticholinesterases.

The highly polar quaternary ammonium group of glycopyrronium bromide limits its passage across lipid membranes, such as the blood-brain barrier.

Glycopyrronium bromide has a specific effect on salivary and sweat gland activity with little effect on pupil size, visual accommodation or heart rate. Following a dose of 0.2 mg intramuscularly, sweat gland activity and salivation are markedly inhibited for over 6 hours.

Pharmacokinetics

Absorption from the intramuscular site of administration is almost complete and as rapid as that following intravenous administration. As would be anticipated from a quaternary compound, oral absorption is poor and erratic.

Glycopyrronium bromide is a superior drug when compared with atropine. A dose of 0.4 mg I.M. inhibits salivation by over 90% and produces only slight slowing of the heart rate. Atropine has been shown in doses of 2.0 mg I.M. to inhibit salivation by approximately 80% but produces a rise in heart rate of greater than 80%.

Studies involving radio-labelled glycopyrronium bromide (200 mcg intravenously) show that the initial distribution phase is extremely rapid, approximately 90% of the radioactivity disappeared from plasma within five minutes and being rapidly excreted in bile and urine.

Approximately 10 – 20 % is absorbed from the gastrointestinal tract and is excreted in bile and urine as unchanged drug and metabolites. Like all quaternary ammonium compounds it penetrates the blood-brain barrier only poorly.

List of excipients

Sodium Chloride

Hydrochloric Acid

Water for injection

Incompatibilities

Glycopyrronium bromide Injection has been shown to be physically incompatible with the following agents commonly used in anaesthetic practice: Diazepam, Dimenhydrinate, Methohexitone Sodium, Pentazocine, Pentobarbitone Sodium, Thiopentone Sodium.

Storage Condition

Store below 30°C, protect from light.

If only part of an ampoule is used, discard the remaining solution.

Keep medicines out of reach of children.

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Shelf Life

24 months

Pack Size

Glycopyrronium bromide Injection 1 mL and 3mL is presented in clear Open Point Cut (OPC) glass ampoules, packed in cartons to contain 10 x 1ml and 10 x 3ml.

Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Manufactured By:

Swiss Parenterals Limited
Plot No 808 809 And 810,
Kerala Industrial Estate Gidc,
Ahmedabad, 382220, INDIA.

Product Registration Holder

Unimed Sdn. Bhd.,
53, Jalan Tembaga SD5/2B,
Bandar Sri Damansara, 52200
Kuala Lumpur, Malaysia.

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