pharmaniaga®

Atropine Sulphate 1mg/ mL Injection

COMPOSITION
Each ampoule contains Atropine Sulphate 1mg/mL.

PRODUCT DESCRIPTION
A clear and colourless solution.

PHARMACODYNAMICS
An antimuscarinic agent with both central and peripheral actions. Its major action is the competitive antagonism to acetylcholine and other muscarinic agents, at the receptor or exocrine glands, smooth and cardiac muscles.

PHARMACOKINETICS
Readily absorbed from mucous membranes, skin and GIT, but not from stomach. Small amounts are secreted in milk; about 50% bound to plasma proteins. In man, about 50% of a dose is metabolised but the pathways involved are not elucidated; traces of tropic acid and atropine formed as a result of hydrolysis, are detectable in the urine.

The guinea-pig, as demonstrated by experiments in vitro metabolises atropine via N-oxidation and demethylation. In 24 hours, 85 to 88% of a dose is excreted in the urine, 50% of the dose is excreted unchanged, less than 2% is excreted as tropic acid, and about 30% is excreted as unknown metabolites.

INDICATION
Pre-anaesthetic medication usually in conjugation with morphine sulphate. In conjugation with neostigmine methyl sulphate to reverse the effects of non-depolarising muscle relaxants. Smooth muscle spasm in conditions such as renal and biliary colic. In the management of arrhythmias and in the treatment of bradycardia or asystole due to overdosage with parasympathomimetic agents. Atropine has also been used in the suppression of gastro-intestinal motility in the treatment of peptic ulcer, and diagnosis of colicky pain, as an antidote in carbamate and (with pralidoxime) organo-phosphorus insecticide poisoning.

RECOMMENDED DOSAGE
Atropine Sulphate Injection may be given by subcutaneous, intramuscular or direct intravenous injection. The intravenous injection should be administered slowly. Atropine Sulphate Injection should not be added to any intravenous infusion solutions for administration.

Cardiopulmonary Resuscitation: The usual adult dose is 0.5-1 mg IV, which may be repeated at 5 minutes intervals until the desired heart rate is achieved. The total dose should not exceed 2 mg. The usual pediatric dose is 0.02 mg/kg (maximum 0.5 mg) IV, which may be repeated at 5 minute intervals until the desired heart rate is achieved. The total dose should not exceed 1 mg.

Premedication: 300 to 600 micrograms Atropine Sulfate Injection may be given intramuscularly or subcutaneously 30 to 60 minutes prior to induction of anesthesia. Alternatively 300 to 600 micrograms intravenously may be given immediately before induction of anaesthesia.

Children: 65 micrograms atropine subcutaneously for premature infants, 100 micrograms for full term infants and 200 micrograms for infants between 6 months to 1 year. In children older than 1 year atropine may be given intramuscularly or subcutaneously at 10 to 20 micrograms/kg.

Reversal of Competitive Neuromuscular Block: May be given by slow intravenous injection in conjunction with an anticholinesterase agent (eg. neostigmine, physostigmine). 600 micrograms to 1.2 mg atropine for each 0.5 to 2.5 mg neostigmine methylsulfate in adults and 0.02 mg/kg atropine for each 0.04 mg/kg neostigmine methylsulfate in children.

Organophosphate Poisoning: 1 to 2 mg atropine may be given intravenously. Additional 2 mg doses may be administered intramuscularly or intravenously every 5-60 minutes until symptoms subside; and repeated if they reappear. For severe cases 2-6 mg may be administered intravenously, with subsequent additional doses of 2-6 mg being administered until symptoms subside.
Doses up to 50 mg may be required within the first 24 hours. With severe cases atropine therapy should be withdrawn gradually to avoid sudden recurrence of symptoms. A cholinesterase reactivator (eg. pralidoxime) is administered concomitantly.

The dose for children is 0.05 mg/kg IM or IV, repeated at 10 to 30 minute intervals until symptoms subside.

ROUTE OF ADMINISTRATION
Parenteral
(Intramuscular, Subcutaneous or Intravenous Injection)

CONTRAINDICATIONS
Closed-angle glaucoma, gastric or duodenal ulcer causing stenosis and significant gastric retention, urinary retention in prostatic hypertrophy, paralytic ileus, debilitated patients with oesophageal reflux or oesophagitis.

Contraindicated in situations where ambient temperature is high since hyperpyrexia may follow, especially in children. Also contraindicated in nursing mothers as atropine will diminish milk flow. Should not be given to patients with myasthenia gravis unless it is given to reduce adverse muscarinic effects of an anticholinesterase agent.

WARNINGS AND PRECAUTIONS
It should be used with caution in children and in elderly patients. It should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure, and in cardiac surgery. It should be given with care to patients with hypertension, fever, diarrhoea, acute myocardial infarction.

INTERACTION WITH OTHER MEDICAMENTS
The effect of atropine and other antimuscarinic agents may be enhanced by the concomitant administration of other drugs with antimuscarinic properties, such as amantadine, some antihistamines, butyrophenones and phenothiazines and tricyclic antidepressant.

Incompatibilities
Atropine sulphate injection is reported to be physically incompatible with norepinephrine bitartrate, metaraminol bitartrate and sodium bicarbonate injections. A haze or precipitate may form within 15 minutes when atropine sulphate injection is mixed with methohexital sodium solutions.

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION
Pregnancy
Atropine sulphate crosses placenta. There is insufficient evidence to establish the safety of atropine in human pregnancy. It should therefore be used during pregnancy only if considered essential by the physician.

Lactation
Atropine sulphate is excreted in breast milk and infants of nursing mothers may exhibit some effects of the drug. Infants are usually very sensitive to the effects of anticholinergic drugs. Atropine should therefore only be used during breast feeding if considered essential by the physician.

SIDE EFFECTS
Dryness of mouth with difficulty in swallowing, thirst, pupils dilatation with loss of accommodation and photophobia, increase intra-ocular pressure, flushing and dryness of skin, bradycardia followed by tachycardia, with palpitations and arrhythmias, urinary retention, constipation, occasionally vomiting, giddiness and staggering may occur. Rapid and stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, hallucinations passing into delirium and a rash may appear on the face and upper trunk

SYMPTOMS AND TREATMENT OF OVERDOSAGE
Symptoms
Tachycardia, rapid or stertorous breathing, hyperpyrexia, restlessness, confusion and excitement, and hallucinations passing into delirium, dilated pupils, and a hot flush, dry skin, paranoid and psychotic reactions, seizures or convulsion, CNS depression, coma, circulatory and respiratory failure and death.

Treatment
Physostigmine salicylate 1-2 mg should be injected SC, IM or IV to control the central and peripheral effects, repeated every 1-2 hours as necessary. Excitement may be controlled by small doses of a short acting barbiturate such as thiopentone sodium 100 mg. Supportive therapy may require oxygen and assisted respiration, ice-bags or alcohol sponges for hyperpyrexia, especially in children, bladder catheterisation and the administration of fluids. Diazepam may be given to control marked excitement and convulsion; phenothiazines should not be given as they may exacerbate antimuscarinic effects.

Effect on Ability to Drive and Use Machine
Atropine sulfate may cause drowsiness or blurred vision and patients should be used advised accordingly.

STORAGE CONDITION
Store below 30°C. Protect from light. Retain in carton until time of use.
Do not use if solution contains particles, growth, turbidity or if there is any change of appearance.

SHELF LIFE
3 years from date of manufacture.

DOSAGE FORMS AND PACKAGING AVAILABLE:
10 x 1mL ampoule (clear).

PRODUCT REGISTRATION HOLDER/MANUFACTURER:
PHARMANIAGA LIFESCIENCE SDN BHD (198201002939)
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