

Summary of Product Characteristics

1. **TRADE NAME OF THE MEDICINAL PRODUCT**

Atropine Sulphate Injection BP 600mcg/ml.

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Atropine Sulphate BP 0.06% w/v.

3. **PHARMACEUTICAL FORM**

Sterile solution for injection.

4. **CLINICAL PARTICULARS**

4.1 Therapeutic indications

1. Drying secretions prior to anaesthesia.
2. Reversal of excessive bradycardia.
3. Indicated with neostigmine for reversal of neuromuscular block.

4.2 Posology and method of administration

Adults

Bradycardia

Management of bradycardia of acute myocardial infarction: Initial dose 300 – 600mcg intravenously, the dose may be increased by incremental doses of 100mcg up to 1mg if necessary.

Caution is required as atropine may aggravate ischaemia or infarction.

Treatment of bradycardia or asystole due to overdosage with parasympathetic agents: 1-2mg subcutaneously, intramuscularly or intravenously.

Drying secretions

300 – 600mcg subcutaneously or intramuscularly 30 – 60 minutes prior to induction of anaesthesia. Alternatively, 300 – 600mcg may be given intravenously immediately prior to induction of anaesthesia.

Reversal of competitive neuromuscular block

0.6 – 1.2mg by slow intravenous injection for control of muscarinic side effects of neostigmine in reversal of competitive neuromuscular block. Atropine should not be given routinely with neostigmine as it may mask signs of overdose.

- 2 -

Children aged 1 year and over

Caution should be exercised in children and reduced doses are necessary.

Drying secretions: 20mcg/kg intramuscularly 30 – 60 minutes prior to induction of anaesthesia. This dose should be reduced on hot days or in fever.

Other indications are not recommended for children.

Elderly

Caution should be exercised in the elderly and reduced doses may be required.

Routes of administration: Intravenous, intramuscular or subcutaneous injection.

4.3 Contra-indications

Known hypersensitivity to atropine, prostatic enlargement, paralytic ileus, pyloric stenosis, closed angle glaucoma or patients with narrow angle between iris and cornea. Atropine should not be given to patients, particularly children, when ambient temperatures are high due to the risk of provoked hyperpyrexia.

4.4 Special warnings and precautions for use

Atropine should be used with caution in children and the elderly, patients with ulcerative colitis as ileus and megacolon may result and those with diarrhoea. Caution is required in patients having a fever, conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery or acute myocardial infarction. Atropine should be given with care to patients with hypertension. Extreme caution is necessary in patients with myasthenia gravis or autonomic neuropathy.

Caution is required when atropine is administered systemically to patients with chronic obstructive pulmonary disease, as a reduction in bronchial secretions may lead to the formation of bronchial plugs.

Antimuscarinics may delay gastric emptying, decrease gastric motility and relax the oesophageal sphincter. They should be used with caution in patients whose conditions may be aggravated by these effects e.g. reflux oesophagitis.

4.5 Interactions with other medicaments and other forms of interaction

Effects of atropine may be enhanced by concomitant administration of drugs having antimuscarinic properties. The reduction in gastric motility caused by atropine may affect absorption of other drugs.

- 3 -

4.6 Pregnancy and lactation

Safety in human pregnancy has not been established although atropine does cross the placenta. Atropine may have antimuscarinic effects in infants. Therefore it is not advisable to administer atropine during pregnancy or breast feeding unless considered essential.

4.7 Effects on ability to drive and use machines

None as used on sedentary patients.

4.8 Undesirable effects

Common side effects include dryness of the mouth with difficulty in swallowing and talking, thirst, mydriasis with cycloplegia and photophobia, flushing and dryness of skin, transient bradycardia followed by tachycardia, palpitations and arrhythmias, urinary retention, constipation.

Other reported side effects include anaphylaxis, urticaria and rash occasionally progressing to exfoliation.

Occasionally vomiting and dizziness. Retrosternal pain may occur due to gastric reflux. Rare occurrences include confusional states and fever.

Atropine may cause raised intra-ocular pressure and mental confusion especially in the elderly.

4.9 Overdosage

Symptoms: Flushing and dryness of the skin (rash may appear on the face and upper trunk), tachycardia, rapid respiration, hyperpyrexia, CNS stimulation (restlessness, confusion, excitement, paranoid and psychotic reactions, hallucinations and delirium and occasionally seizures and convulsions). Severe overdose may be indicated by CNS depression, coma, circulatory and respiratory failure and death.

Treatment: Supportive therapy as necessary. Neostigmine or carbachol antagonise peripheral adverse effects. In children the body surface should be kept moist.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atropine is an antimuscarinic alkaloid with both central and peripheral actions. It first stimulates and then depresses the central nervous system and has antispasmodic actions on smooth muscle and reduces secretions, especially salivary and bronchial secretions.

- 4 -

5.2 Pharmacokinetic properties

Rapidly cleared from blood and distributed throughout the body.

Completely metabolised in the liver and excreted in the urine as unchanged drug and metabolites.

Atropine crosses the placenta and traces are found in breast milk. Atropine crosses the blood brain barrier.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sulphuric Acid BP
Water for Injections HSE

6.2 Incompatibilities

Atropine is incompatible with alkaloids, tannic acid and mercury salts.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

1ml neutral glass ampoules in packs of 5, 10 or 100.

6.6 Instructions for use/handling

None stated.

7. **MARKETING AUTHORIZATION HOLDER**

Antigen International Limited
Roscrea
Co. Tipperary
Ireland

8. **MARKETING AUTHORIZATION NUMBER**

PL 02848/0211

9. **DATE OF FIRST AUTHORIZATION**

3 April 2000

10. **DATE OF (PARTIAL) REVISION OF THE TEXT**

February 2000