

Product Summary

1. Trade Name of the Medicinal Product

Atropine Sulphate Injection B.P. 500 micrograms/1ml

2. Qualitative and Quantitative Composition

Each 1ml of solution contains 500 micrograms of Atropine Sulphate B.P.

3. Pharmaceutical Form

Clear, colourless, sterile, aqueous solution intended for parenteral administration to human beings

Clinical Particulars

4.1. Therapeutic Indications

- 1) In anaesthesia, to reduce the risk of vagal inhibition of the heart and to reduce salivary and bronchial secretions.
- 2) In the treatment of cholinergic crisis of myasthenia gravis.
- 3) In conjunction with neostigmine used to reverse the effects of non-depolarising muscle relaxants.
- 4) In the treatment of poisoning by certain cholinesterase inhibitors e.g. organophosphorous compounds.
- 5) During cardiopulmonary resuscitation to counteract excessive vagal tone on the heart

4.2. Posology and Method of Administration

1) Use in Anaesthesia

Adults (including the elderly) : The usual dose is 0.3 to 0.6mg (300 micrograms to 600 micrograms).

Children :

Premature Infants : 65 micrograms

Full-term Infants : 100 micrograms

6 months - 1 year : 200 micrograms

Over one year : 10 - 20 micrograms/kg bodyweight

2) Treatment of cholinergic crisis of myasthenia gravis

Adults : The usual dose is 0.4 to 2.0mg intravenously, which may be increased according to patients response.

3) In conjunction with neostigmine used to reverse the effects of nondepolarising muscle relaxants

Adults : The usual dose is 0.6 to 1.2mg given by slow intravenous injection.

Atropine should be administered before neostigmine.

4) Treatment of poisoning by certain cholinesterase inhibitors

Adults : From 1.2mg, increased according to patients response.

5) Use during Cardiopulmonary Resuscitation

Adults : A dose of 0.2 to 0.5mg may be given intravenously and repeated if necessary. Persistent bradycardia should be controlled by the insertion of a pacemaker as soon as possible.

Route of administration : By subcutaneous, intramuscular or intravenous injection.

4.3. Contra-indications

Use in patients hypersensitive to anticholinergic agents.

Use in paralytic ileus or pyloric stenosis.

Use in patients with closed-angle glaucoma or prostatic hypertrophy.

4.4. Special Warnings and Precautions for Use

Atropine should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery.

Atropine should be used only with extreme caution in toxic pyrexial children, or in high ambient temperatures, because of the danger of hyperpyrexia.

When used to treat a cholinergic crisis in myasthenia gravis, all anticholinesterase medication should be withdrawn, if necessary for several days.

Doses of Atropine up to 1mg are mildly stimulant to the central nervous system. Higher doses may induce mental disturbances and depression of the central nervous system. Children and elderly people are particularly susceptible.

Care is required when using atropine in the presence of acute myocardial ischaemia or infarction as the ischaemia or infarction may be worsened.

4.5. Interactions with other Medicaments and other forms of Interaction

The effects of the atropine may be enhanced by the concomitant administration of other drugs with anticholinergic properties e.g. some antihistamines, phenothiazines, tricyclic anti-depressants, amantadine, butyrophenones.

Atropine should be used cautiously during ether anaesthesia since the sympathomimetic effects of this agent are likely to be potentiated.

4.6. Pregnancy and Lactation

Atropine crosses the placenta and the drug should only be used during pregnancy and lactation if considered essential by the physician.

4.7. Effects on Ability to Drive and Use Machines

Not applicable, as the patient would be too ill.

4.8. Undesirable Effects

Side effects include dry mouth, dysphagia, dry skin, thirst, dilated pupils with loss of accommodation and photophobia, increased intraocular pressure, palpitation, arrhythmias, constipation and urinary retention.

4.9. Overdose

Toxic doses may cause CNS stimulation with restlessness, hallucinations, delirium and occasionally convulsions. In severe intoxication, there may be central depression, circulatory and respiratory failure and coma.

Symptomatic treatment includes sponging and cold packs for fever, paraldehyde or diazepam for excitement or convulsions and oxygen and artificial respiration for respiratory depression. The use of physostigmine as an antidote may be considered.

Pharmacological Properties

5.1. Pharmacodynamic Properties

Atropine Sulphate is an anticholinergic agent. Atropine is a competitive antagonist of the actions of acetylcholine on muscarinic receptors. It has peripheral and central actions, although it has almost no detectable effect on the CNS in doses that are used clinically. The peripheral effects of atropine include increase in heart-rate, decrease in production of saliva, sweat, bronchial and intestinal secretions and a decrease in intestinal motility.

5.2. Pharmacokinetic Properties

Following subcutaneous or intramuscular injection, atropine enters the circulation and is distributed throughout the body. It crosses the blood-brain barrier. Hepatic metabolism accounts for the elimination of about half a dose and the remainder is excreted unchanged in the urine. Atropine has a half-life of approximately 4 hours. It crosses the placenta and traces appear in breast milk.

5.3. Preclinical Safety Data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

Pharmaceutical Particulars

6.1. List of Excipients

Dilute Sulphuric Acid B.P.

Water for Injections B.P. (in bulk)

6.2. Incompatibilities

Atropine Sulphate Injection is incompatible with alkalis, tannic acid and mercury salts

6.3. Shelf Life

Unopened : 4 years

After reconstitution : not applicable

After first opening : 4 years*

* If only part of an ampoule is used, the remainder should be discarded

6.4. Special Precautions for Storage

Store below 25°C.

Protect from light.

6.5. Nature and Contents of Container

1ml, clear glass ampoules, glass type 1 Ph.Eur. borosilicate glass packed in cardboard cartons to contain 10 x 1ml ampoules.

6.6. Instruction for Use/Handling

For S.C., I.M. or I.V. injection.

Use as directed by the physician.

Keep out of reach of children.

If only part used, discard the remaining solution.

Administrative Data

7. Marketing Authorisation Holder

Antigen International Ltd.,

Roscrea,

Co. Tipperary,

Ireland.

8. Marketing Authorisation Number

PL 02848/5911R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/02/2009

10 DATE OF REVISION OF THE TEXT

26/02/2009