SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Atropine Sulfate 1mg in 5ml Solution for injection in pre-filled syringe.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml syringe contains 1 mg Atropine sulfate
Each 1ml of solution for injection contains 0.2 mg Atropine sulphate
For the full list of excipients, see section 6.1.
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3 PHARMACEUTICAL FORM

Solution for injection in pre-filled syringe. Clear and practically particulate free solution pH 3 - 4.5.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Reversal of excessive of bradycardia. The administration is given in the algorithm for the emergency treatment of Peri - arrest arrhythmias produced by European Resuscitation Council's and Resuscitation Council (UK).

4.2 Posology and method of administration

Adults and children over 12 years

Initially 0.5mg by intravenous injection and then increments of 0.5mg to a maximum of 3mg.

Paediatric population

Not recommended.

Elderly

As for Adults.

Method of administration:

Atropine 1mg in 5ml is administered by intravenous injection.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in 6.1

- Closed-angle glaucoma
- Risk of urinary retention because of prostatic or urethral disease
- Myasthenia gravis unless given in conjunction with anticholinesterase
- Breast-feeding (see section 4.6).
- Achalasia of the oesophagus

4.4 Special warnings and precautions for use

Use with caution in case of:

Prostatic enlargement

Renal or hepatic insufficiency

Cardiac insufficiency, arrhythmias, hyperthyroidism

Chronic obstructive pulrnonary disease, as a reduction in bronchial secretions may lead to the formation of bronchial plugs

Paralytic ileus, intestinal atonia in elderly, toxic megacolon

Pyloric stenosis

Fever, or when ambient temperature is high

In the elderly, who are more susceptible to adverse effects.

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4.5 Interaction with other medicinal products and other forms of interaction

Combinations to be taken into account

Other medicinal products with anticholinergic activity such as tricyclic antidepressants, some H1-anithistamines, antiparkinsonian medicines, disopyramide, mequitazine, phenothiazines, neuroleptic medicines, atropinic antispasmodics,clozapine and quinidine, because of the risk of potentialisation of atropinic adverse effects (urinary retention, constipation, dry mouth).

4.6 Fertility, pregnancy and lactation

Pregnancy

Studies in animal have shown a teratogenic effect of atropine in one species with very high doses.

Data on a limited number of exposed pregnancies indicate no adverse effects of atropine on pregnancy or on the health of the foetus/new-born child.

Atropine passes the placenta barrier.

To date, no other epidemiological data are available.

Atropine should not be used during pregnancy unless clearly necessary.

Breast-feeding

Atropine is excreted in breast milk, and may cause neurological toxicity in the infant. Moreover atropine inhibits lactation.

Breast-feeding is thus contraindicated if atropine should be used.

Fertility

There are no preclinical fertility data with atropine, and no epidemiological data.

4.7 Effects on ability to drive and use machines

Atropine may cause confusion or blurred vision and patients should be advised of it.

4.8 Undesirable effects

The most commonly reported adverse events are due to the action of atropine on muscarinic and, at high doses, on nicotinic receptors. These effects are dose-related and usually reversible when therapy is discontinued.

Immune system disorders:

Anaphylaxis

Psychiatric disorders:

Nervousness, confusional state, especially in the elder1y. At higher doses hallucinations, restlessness, and delirium.

Eye disorders:

Dilatation of the pupils with loss of accommodation and photophobia, decrease in lachrymal secretion, increase in intraocular pressure.

Cardiac disorders:

Tachycardia, palpitations, arrhythmias.

Vascular.

Flushing

Respiratory, thoracic and mediastinal disorders:

Thickening of bronchial secretions.

Gastrointestinal disorders:

Dry mouth, nausea, vomiting, and constipation.

Renal and urinary disorders:

Urinary retention.

Skin and subcutaneous tissue:

Dry skin

General:

Thirst

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms

Flushing and dryness of the skin, dilated pupils, dry mouth and tongue, tachycardia, rapid respiration, hyperpyrexia, nausea, vomiting. Symptoms of CNS stimulation include restlessness, confusion, hallucinations, paranoid and psychotic reactions, incoordination, delirium and occasionally convulsions. In severe overdose, CNS depression may occur with coma, circulatory and respiratory failure and death.

Treatment

Treatment of overdosage with atropine sulfate injection consists of symptomatic and supportive therapy, control of delirium. General measures include: reduction of body temperature, administration of fluids orally or intravenously, monitoring of ECG or excitement with diazepam, urinary catheterisation to avoid urinary retention. The use of physostigmine as an antidote to atropine is controversial.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anticholinergic agents.
ATC code: A03BA01.

Atropine is an antimuscarinic agent which competitively antagonises acetylcholine at postganglionic nerve endings, thus affecting receptors in the exocrine glands, smooth muscle, cardiac muscle and the central nervous system.

Peripheral effects include decreased production of saliva, sweat, nasal, lachrymal and gastric secretions, decreased intestinal motility and inhibition of micturition.

Atropine increases sinus rate and sinoatrial and AV conduction. Usually heart rate is increased, but there may be an initial bradycardia.

Atropine inhibits secretions throughout the respiratory tract and relaxes bronchial smooth muscle producing bronchodilation.

5.2 Pharmacokinetic properties

Absorption

Following intravenous administration, the peak increase in heart rate occurs within 2 to 4 minutes. Peak plasma concentrations of atropine after intramuscular administration are reached within 30 minutes, although peak effects on the heart, sweating and salivation may occur 1 hour after intramuscular administration.

Distribution

Plasma levels after intramuscular and intravenous injection are comparable at 1 hour. Atropine is distributed widely throughout the body and crosses the blood brain barrier and the placenta barrier.

Elimination

The elimination half-life is about 2 to 5 hours. Up to 50% of the dose is protein bound.

Biotransformation

Atropine is incompletely metabolised in the liver and is excreted in the urine as unchanged drug and metabolites. About 50% of the dose is excreted within 4 hours and 90% in 24 hours.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections,

Sulfuric Acid (for pH adjustments),

Nitrogen

6.2 Incompatibilities

Atropine Sulfate injection is reported to be physically incompatible with bromides, iodides, alkalis, noradrenaline bitartrate, metaraminol bitartrate and sodium bicarbonate. A haze or precipitate may form within 15 minutes when Atropine Sulfate is mixed with methohexital sodium solutions.

6.3 Shelf life

18 Months

6.4 Special precautions for storage

Store below 25ºC. Protect from light.

6.5 Nature and contents of container

Sterile aqueous solution for injection in Glass (Type I) 5ml prefilled syringe.

Each syringe is packaged in a lidded blister inside a carton.

No needle is provided with this syringe.

6.6 Special precautions for disposal

Use once and discard any remaining solution.

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

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7 MARKETING AUTHORISATION HOLDER

Aurum Pharmaceuticals Ltd

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RM3 8UG

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8 MARKETING AUTHORISATION NUMBER(S)

PL 12064/0035

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 January 1998

10 DATE OF REVISION OF THE TEXT

12/01/2017