1 NAME OF THE MEDICINAL PRODUCT

Atropine Sulfate 600 micrograms Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Atropine sulfate 600 micrograms.

Excipients: lactose.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet for oral use

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Non-ulcer dyspepsia

Irritable bowel syndrome

Diverticular disease

4.2 Posology and method of administration

Adults
0.6mg - 1.2mg as a single night time dose.

Elderly and Children
Atropine should be used with caution employing a suitably reduced dose.

4.3 Contraindications

Atropine is contraindicated in patients with prostatic enlargement, as it may lead to urinary retention.

Atropine should not be used in patients with paralytic ileus or pyloric stenosis.

Atropine is contraindicated in angle-closure glaucoma or in patients with a narrow angle between the iris and the cornea as it may raise intra-ocular pressure and precipitate an acute attack.

Atropine is contra-indicated in myasthenia gravis (except to reduce muscarinic side-effects of anticholinesterases).

4.4 Special warnings and precautions for use

Use with caution in patients with urinary retention, acute myocardial infarction, hypertension, conditions associated with tachycardia (including hyperthyroidism, cardiac insufficiency, cardiac surgery), pyrexia and diarrhoea.

Use of atropine in patients with ulcerative colitis may lead to toxic megacolon and ileus.

Increased side effects may be seen in children and the elderly, and in patients with Down's syndrome.

Atropine may aggravate gastro-oesophageal reflux.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol: Marked impairment of attention can occur with alcohol, sufficient to make driving more hazardous (see 4.7 Effects on Ability to Drive and Use Machinery).

Anti-arrhythmics: Increased antimuscarinic side-effects may occur with disopyramide. The absorption of mexiletine can be delayed by atropine but the extent of absorption is unaltered and no special precautions are necessary.

Anticholinergics: Many drugs have antimuscarinic effects; concomitant use of two or more such drugs can increase side-effects such as dry mouth, urine retention, and constipation; concomitant use can lead to confusion in the elderly.

Antidepressants: Increased antimuscarinic side-effects may occur with tricyclic antidepressants and mono-amine oxidase inhibitors (MAOIs).

Antifungals: The absorption of ketoconazole can be reduced by atropine.

Antihistamines: Increased antimuscarinic side-effects may occur with some antihistamines.

Antipsychotics: Increased antimuscarinic side-effects may occur with phenothiazines and clozapine.

Antivirals and Dopaminergics: Increased antimuscarinic side-effects may occur with amantadine. The absorption of levodopa may possibly be reduced when administered with antimuscarinic agents.

Metoclopramide and domperidone: Possible antagonism of gastrointestinal effects.

Nitrates: The common side-effect of a dry mouth with atropine may result in the failure of sublingual nitrates to dissolve, thereby reducing their effectiveness.

Parasympathomimetics: Possible antagonism of effect of parasympathomimetics.

Phenylephrine: Hypertensive and other serious adverse effects of phenylephrine absorbed from eye drops may be markedly increased by atropine

4.6 Fertility, pregnancy and lactation

Atropine crosses the placenta and traces are found in breast milk. It should therefore only be used with caution.

4.7 Effects on ability to drive and use machines

Atropine may cause visual disturbances, giddiness and staggering. In addition, marked impairment of attention can occur with alcohol (see 4.5 Interactions). If affected, patients should be cautioned against driving a car or operating machinery.

4.8 Undesirable effects

Some of the central effects of atropine seen at toxic doses (see section 4.9) may also occur at therapeutic doses.

Immune system disorders
Hypersensitivity.
In rare cases a fever may develop.

Psychiatric disorders
Confusional states (particularly in the elderly).

Nervous system disorders
Occasionally giddiness and staggering may occur.

Eye disorders
Dilation of the pupils with loss of accommodation and photophobia. Increased intra-ocular pressure. In rare cases, angle-closure glaucoma may develop.

Cardiac disorders
Transient bradycardia, followed by tachycardia, palpitations and arrhythmias.

Respiratory, thoracic and mediastinal disorders
Bronchial secretions may be reduced, with formation of mucous plugs.

Gastrointestinal disorders
Dry mouth with difficulty in swallowing, thirst. Occasionally nausea and vomiting may occur. A reduction in the tone and mobility of the gastro-intestinal tract may lead to constipation. Increased gastric reflux may result in retrosternal pain.

Skin and subcutaneous tissue disorders
Flushing and dryness of the skin. Rashes.

Renal and urinary disorders
Urinary urgency, difficulty or retention.

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

There is considerable variation in susceptibility to atropine; recovery has occurred even after 1g, whereas deaths have been reported from doses of 100mg or less for adults and 10mg for children.

Symptoms of overdose:
In overdose, the peripheral effects become more pronounced such as dilation of pupils, continuing blurred vision, or changes in near vision, severe dryness of mouth, nose or throat, dizziness and drowsiness. Other symptoms such as rapid respiration, increased respiratory rate, difficulty in breathing, increased heartbeat, hypertension, hyperthermia, fever, muscle weakness, inhibition of micturition, nausea and vomiting may occur. A rash may appear on the face, neck or upper trunk, and there may be unusual warmth, dryness or flushing of the skin. Toxic doses also cause CNS stimulation marked by nervousness, restlessness, irritability, confusion, excitement, ataxia, incoordination, slurred speech, paranoid and psychotic reactions, hallucinations and delirium and occasionally seizures. In severe overdose, central stimulation may give way to CNS depression, coma, circulatory and respiratory failure and death.

Treatment of overdose:
If a patient presents within an hour of an overdose of atropine by mouth, the stomach may be emptied (but only if a life-threatening amount has been ingested) or activated charcoal given to reduce absorption. Diazepam may be given to control marked excitement and convulsions. Hypoxia and acidosis should be corrected. If metabolic acidosis persists despite correction of hypoxia and adequate fluid resuscitation consider correction with intravenous sodium bicarbonate. Antiarrhythmics are not recommended if arrhythmias develop. Phenothiazines should not be given as they may exacerbate antimuscarinic effects. Supportive therapy should be given as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atropine is an antimuscarinic agent. These substances are competitive inhibitors of acetylcholine at muscarinic receptors of autonomic effector sites with parasympathetic innervation.

5.2 Pharmacokinetic properties

Atropine is readily absorbed from the gastro-intestinal tract and mucous membranes. It is absorbed from the eye and to a lesser extent through intact skin.

It is rapidly cleared from the blood and is distributed through the body, crossing the blood-brain barrier. It is completely metabolised in the liver and is excreted in the urine as unchanged drug and metabolites.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose
Magnesium stearate
Stearic acid
Ethanol 96%

6.2 Incompatibilities

None known

6.3 Shelf life

Three years in polypropylene/polyethylene containers.

Two years in strip packs.

6.4 Special precautions for storage

Do not store above 25ºC

Store in the original container

6.5 Nature and contents of container

Polyethylene or polypropylene containers with tamper evident closure strips of 28, 30, 56, 60, 84, 90 or 100 tablets.

Strip packs of 28, 30, 56, 60, 84 or 90 tablets.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Wockhardt UK Ltd
Ash Road North
Wrexham
LL13 9UF
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 29831/0021

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/03/1987

10 DATE OF REVISION OF THE TEXT

23/02/2016