1.3.1.1 PROFESSIONAL INFORMATION

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorize any deviation from such information or such format (Refer to Regulation 9 of the Act).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition
4. Pharmacological classification
5. Pharmacological action (pharmacokinetics, pharmacodynamics and summary of clinical studies, where applicable)
6. Indications
7. Contra-indications
8. Warnings
9. Interactions
10. Pregnancy and lactation
11. Dosage and directions for use
12. Side effects and special precautions
13. Known symptoms of over dosage and particulars of its treatment
14. Identification
15. Presentation
16. Storage instructions
17. Registration number (or reference number)
18. Name and business address of the applicant
19. Date of publication of this professional information

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S4**

PROPRIETARY NAME **ADCO ATROPINE 0,5 mg/ml Injection**

(AND DOSAGE FORM): **ADCO ATROPINE 1 mg/ml Injection**

COMPOSITION:

Atropine Sulphate 0,5 mg in 1 ml

Atropine Sulphate 1 mg in 1 ml

PHARMACOLOGICAL CLASSIFICATION:

A.5.4 (Anticholinergics)

PHARMACOLOGICAL ACTION:

ADCO ATROPINE Sulphate Injection acts as a parasympatholytic agent with central and peripheral actions.

INDICATIONS:

ADCO ATROPINE Sulphate Injection can be used in the treatment of conditions where anticholinergic effects are required.

CONTRA-INDICATIONS:

Patients with prostatic enlargement, paralytic ileus or pyloric stenosis, closed angle glaucoma or with a narrow angle between the iris and the cornea, coronary insufficiency or cardiac failure.

DOSAGE AND DIRECTIONS FOR USE:

Premedication:

0,3 - 0,6 mg IV immediately before anaesthesia to diminish the risk of vagal inhibition of the heart and to reduce salivary and bronchial secretions.

Bradycardia:

0,3 - 0,6 mg IV for the management of bradycardia. This dose may subsequently be increased according to the patient's response.

Note: The volume to be administered should be checked at the time of extraction from the ampoule, prior to injection.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Dryness of the mouth, dilatation of the pupils with loss on accommodation and photophobia, increased intra-ocular pressure, flushing and dryness of the skin, tachycardia with palpitations and arrhythmias, a desire to urinate with the inability to do so, and constipation due to a reduction in the tone and motility of the gastro-intestinal tract may occur. Other effects which may occur are vomiting, giddiness and staggering as well as skin rash. Retrosternal pain may occur due to increased gastric reflux.

Hypersensitivity may occur. High doses may cause postural hypotension. Use with caution in the treatment of elderly males, and in conditions characterized by tachycardia, such as thyrotoxicosis and in cardiac surgery, where it may further accelerate the heart-rate.

Due to the risk of provoking hyperpyrexia, atropine should not be given to patients (especially children) where the ambient temperature is high. Atropine Sulphate should be used cautiously in patients with fever.

In the treatment of Parkinsonism, increases in dosage and transfer to other forms of treatment should be gradual, and anticholinergic agents should not be withdrawn abruptly. If higher doses provoke severe mental disturbances, the drug should be discontinued, but minor reactions may be controlled by reducing the dose until tolerance has developed.

Atropine Sulphate may cause mental confusion, especially in the elderly.

Persons with Down’s syndrome appear to have a increased susceptibility to the action of atropine sulphate, whereas those with albinism may be resistant.

The effects of atropine and other anticholinergic agents may be enhanced by the concomitant administration of other drugs with anticholinergic properties, some antihistamines, butyrophenones, phenothiazianes and tricyclic antidepressants.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Toxic doses of atropine cause tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, and hallucinations passing into delirium. A rash may appear on the face and upper trunk.

In severe intoxication, depression of the central nervous system may occur with circulatory failure and respiratory depression. Treatment of toxic effects is symptomatic.

Physostigmine salicylate has been advocated to control the central and peripheral effects of atropine but is not generally recommended.

Excitement may be controlled by diazepam or a short-acting barbiturate.

IDENTIFICATION:

A clear, colourless solution.

PRESENTATION:

Plastic ampoules containing 0,5 mg Atropine Sulphate in 1 ml.

Plastic ampoules containing 1 mg Atropine Sulphate in 1 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 °C out of reach of children. Protect from light.

REGISTRATION NUMBER:

ADCO ATROPINE 0,5 mg/ml Injection

V/5.4/64

NA: NS2 90/5.4/00195

BW: S2 B9310085

ADCO ATROPINE 1 mg/ml Injection

V/5.4/65

NA: NS2 90/5.4/00196

BW: S2 B9310090

NAME AND BUSINESS ADDRESS OF APPLICANT:

ADCOCK INGRAM CRITICAL CARE (PTY) LTD

1 Sabax Road,

Aeroton

Johannesburg

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08 October 1987