SCHEDULING STATUS: **S2**

PROPRIETARY NAME: ADCO-CYCLIZINE SYRUP

(AND DOSAGE FORM) (SYRUP)

COMPOSITION:

Each 5 ml contains:

Cyclizine HCl 12, 5 mg

Preserved with:

Methyl hydroxybenzoate 0, 12 % m/v

Propyl hydroxybenzoate 0, 02 % m/v

Contains sugar:

Sucrose 0, 5 g

Liquid glucose 1, 25 g

Contains TARTRAZINE

List of excipients: Citric acid monohydrate, permitted colourant and avourant, propylene glycol, purified water, saccharin sodium, sodium citrate and sorbitol.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7 Antihistaminics, anti-emetics and antivertigo preparations.

PHARMACOLOGICAL ACTION:

ADCO-CYCLIZINE SYRUP is a piperazine type antihistamine with anti-emetic properties.

INDICATIONS:

The prevention and treatment of nausea and vomiting, particularly motion sickness and labyrinthine disorders (Ménière syndrome).

CONTRAINDICATIONS:

- Individuals who have previously reacted adversely to cyclizine.

- Pregnancy.

WARNINGS:

Drowsiness, dryness of mouth and blurred vision may occur and be aggravated by simultaneous intake of alcohol, and other central nervous system depressant agents. Patient should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Contains tartrazine which may cause allergic type reactions (including bronchial asthma) in certain individuals. The overall incidence of tartrazine sensitivity is low, it is however frequently seen in patients who also have aspirin sensitivity.

DOSAGE AND DIRECTIONS FOR USE:

To prevent motion sickness ADCO-CYCLIZINE SYRUP should be taken about half an hour before the journey.

Children 6 to 12 years: 10 ml

Children 1 to 5 years: 5 ml

May be given three times daily.

Consult your doctor if no relief is obtained with the recommended dosage.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Drowsiness, dryness of mouth and blurred vision may occur. Other side effects include inability to concentrate, lassitude, dizziness, hypotension, muscular weakness, inco-ordination, gastrointestinal disturbances such as diarrhoea or constipation, epigastric pain, headache, tinnitus, elation or depression, irritability, nightmares, anorexia, diffi culty with micturition, tightness of the chest and tingling, heaviness, and weakness of the hands. In children it may have the same effect as a central stimulant. Blood disorders, including agranulocytosis and haemolytic anaemia, have been reported.

Patients are warned that ADCO-CYCLIZINE SYRUP may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillizers. Since ADCO-CYCLIZINE SYRUP has anticholinergic properties, it should be used with care in conditions liable to be exacerbated or otherwise adversely affected by atropine, such as glaucoma and prostatic hypertrophy. The side effects of anticholinergic drugs such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of ADCOCYCLIZINE

SYRUP.

ADCO-CYCLIZINE SYRUP may affect the metabolism of drugs in the liver. ADCO-CYCLIZINE SYRUP may mask the warning symptoms of damage caused by ototoxic medicines. Restlessness, dizziness and tachycardia may occur if atropine and ADCO-CYCLIZINE SYRUP are used together. Fixed drug eruptions, generalised chorea, and hypersensitivity hepatitis have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS

OF ITS TREATMENT:

Symptoms of acute overdosage arise from effects of the preparation on the central nervous system and include drowsiness, dizziness, inco-ordination, weakness, convulsion, hyperpyrexia and respiratory depression. Agitation, ataxia and hallucinations may occur. Treatment is symptomatic and supportive.

IDENTIFICATION:

Clear, yellow syrup with a naartjie flavour.

PRESENTATION:

Amber glass bottles containing 50 ml and 500 ml and amber PET bottles containing 100 ml.

STORAGE INSTRUCTIONS:

Store below 25 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/5.7/0259

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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