SCHEDULING STATUS: S2

PROPRIETARY NAME: **ADCO-CYCLIZINE 50 mg**

(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:

Each tablet contains:

Cyclizine hydrochloride 50 mg

Contains sugar: Lactose 19,5 mg

List of excipients: Magnesium stearate, maize starch, pregelatinised maize starch, and sodium starch glycollate.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.2. Anti-emetics and antivertigo preparations

PHARMACOLOGICAL ACTION:

Cyclizine is an antihistamine with anti-emetic properties.

INDICATIONS:

ADCO-CYCLIZINE 50 mg is indicated in the prevention and treatment of nausea and vomiting. It is indicated in prophylaxis and treatment of motion sickness, in the symptomatic management of vertigo and labyrinth disorders (Ménière syndrome).

CONTRAINDICATIONS:

ADCO-CYCLIZINE 50 mg is contraindicated in individuals who have previously reacted adversely to cyclizine. **ADCO-CYCLIZINE 50 mg** is contraindicated in pregnancy.

WARNINGS:

ADCO-CYCLIZINE 50 mg tablets may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years: 1 tablet three times a day.

Children 6 to 12 years: ½ tablet three times a day.

For the prevention of motion sickness, one tablet is taken 20 to 30 minutes before departure. This dose may be repeated every 4 to 6 hours if necessary. The dosage for children aged 6 to 12 years is half the adult dosage.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

The most common side effect of **ADCO-CYCLIZINE 50 mg** is sedation which can vary from slight drowsiness to deep sleep, and including inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination. Other side effects include gastrointestinal disturbances such as nausea, vomiting, diarrhoea or constipation and epigastric pain. Headache, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest, and tingling, heaviness and weakness of the hands may occur.

Fixed drug eruptions, generalised chorea, and hypersensitivity hepatitis have been reported after oral administration. In children it may act as a cerebral stimulant. Symptoms of stimulation in adults include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Large doses may precipitate fits in epileptics. Allergy and anaphylaxis may occur. Blood dyscrasias including agranulocytosis and haemolytic anaemia have been reported. **ADCO-CYCLIZINE 50 mg** tablets have anticholinergic properties and should be used with care in conditions such as glaucoma and

prostatic hypertrophy. The effects of atropine and tricyclic antidepressants may be enhanced by **ADCO-CYCLIZINE 50 mg**.

Restlessness, dizziness and tachycardia may occur if atropine and **ADCO-CYCLIZINE 50 mg** are used together. **ADCO-CYCLIZINE 50 mg** tablets may mask the warning symptoms of damage caused by ototoxic drugs and may affect the metabolism of drugs in the liver. **ADCO-CYCLIZINE 50 mg** tablets may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms of acute toxicity arise from effects of the preparation of the central nervous system and include drowsiness, dizziness, inco-ordination, weakness, convulsions, hyperpyrexia and respiratory depression. Agitation, ataxia and hallucinations may occur.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

White tablets scored on one side and embossed with ‘ADCO’ on the other side.

PRESENTATION:

White, polypropylene securitainers with white, LDPE (low-density polyethylene) closures containing 10, 20, 100, 200 and 250 tablets and white, HDPE containers with white, HDPE screw-on closures containing 200 tablets and PVC/Aluminium foil blister packs of 10, 20, 50, 100 & 200 tablets.

STORAGE INSTRUCTIONS:

Store below 25 ºC and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/5.7.2/0386

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

Adcock Ingram Limited

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

09 July 1993

SKEDULERINGSTATUS: S2

EIENDOMSNAAM: **ADCO-CYCLIZINE 50 mg**

(EN DOSEERVORM) **(TABLET)**

SAMESTELLING:

Elke tablet bevat:

Siklisienhidrochloried	50 mg
Bevat suiker: Laktose	19,5 mg

FARMAKOLOGIESE KLASSIFIKASIE:

A 5.7.2 Antiëmetika en antivertigopreparate

FARMAKOLOGIESE WERKING:

Siklisien is ‘n antihistamien met antiëmetiese eienskappe.

INDIKASIES:

ADCO-CYCLIZINE 50 mg word aangedui vir die voorkoming en behandeling van mislikheid en braking. Dit word aangedui vir die voorkoming en behandeling van bewegingsiekte, vir die simptomatiese behandeling van duiseligheid en labirintkwale (Ménière-sindroom).

KONTRA-INDIKASIES:

ADCO-CYCLIZINE 50 mg tablette word teenaangedui by individue wat voorheen ongunstig gereageer het op siklisien. **ADCO-CYCLIZINE 50 mg** word teenaangedui tydens swangerskap.

WAARSKUWINGS:

ADCO-CYCLIZINE 50 mg tablette kan aanleiding gee tot lomerigheid en verswakte konsentrasie, wat vererger kan word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel-onderdrukkers. Pasiënte behoort gewaarsku te word om nie voertuie te bestuur of masjinerie te hanteer of moontlik gevaarlike take te onderneem waar verlies van konsentrasie tot ongelukke kan lei nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes en kinders ouer as 12 jaar: 1 tablet drie keer per dag.

Kinders 6 tot 12 jaar: ½ tablet drie keer per dag.

Vir die voorkoming van bewegingsiekte, een tablet 20 tot 30 minute voor vertrek. Hierdie dosis kan, indien nodig, elke 4 tot 6 uur herhaal word. Die dosis vir kinders tusen die ouderdomme 6 en 12 jaar is helfte van die volwasse dosis.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Die algemeenste newe-effek van **ADCO-CYCLIZINE 50 mg** is sedasie wat kan wissel van ligte lomerigheid tot `n diepe slaap, en sluit in onvermoë om te konsentreer, matheid, duiseligheid, lae bloeddruk, spierswakheid en inkoördinasie. Ander newe-effekte sluit in maagdermongesteldhede soos naarheid, vomering, diaree of hardlywigheid en epigastriese pyn. Hoofpyn, tinnitus, opgewondenheid of neerslagtigheid, prikkelbaarheid, nagmerries, eetlusonderdrukking, moeilike urinering, droë mond, benoude bors en prikkeling, swaarheid en swakheid in die hande kan voorkom.

Middelerupsie, algemene chorea en hipersensitiwiteitshepatitis is al aangemeld na orale toediening. By kinders kan die middel as `n serebrale stimulant werk. Simptome van stimulasie by volwassenes sluit in slaaploosheid, senuweeagtigheid, hartkloppings, bewing, spiertrekkings en konvulsies.

Groot dosisse kan aanvalle by epileptiese pasiënte veroorsaak. Allergieë en anafilakse kan voorkom. Bloedafwykings insluitende agranulositose en hemolitiese bloedarmoede is aangemeld. **ADCO-CYCLIZINE 50 mg** tablette het anticholinergiese eienskappe en behoort met versigtigheid in toestande soos gloukoom en prostaathipertrofie gebruik te word. Die effekte van atropien en trisikliese antidepressante kan verhoog word deur **ADCO-CYCLIZINE 50 mg**.

Rusteloosheid, duiseligheid en hartkloppings kan voorkom as atropien saam met **ADCO-CYCLIZINE 50 mg** toegedien word. **ADCO-CYCLIZINE 50 mg** kan die waarskuwende simptome maskeer van

beskadiging veroorsaak deur ototoksiese geneesmiddels en kan die metabolisme van geneesmiddels in die lewer beïnvloed. **ADCO-CYCLIZINE 50 mg** tablette kan die sedatiewe effek van sentrale senuweestelselonderdrukkers insluitende alkohol, barbiturate, hipnotika, narkotiese analgetika, kalmeermiddels en susmiddels versterk.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Simptome van akute toksisiteit ontstaan as gevolg van die effekte van die preparaat op die sentrale senuweestelsel en sluit lomerigheid, duiseligheid, inkoördinasie, swakheid, konvulsies, hiperpireksie en respiratoriese onderdrukking in. Verontrusting, ataksie en hallusinasies kan voorkom.

Behandeling van oordosering is simptomaties en ondersteunend.

IDENTIFIKASIE:

Wit tablette met breeklyn aan die eenkant en 'ADCO' gebosseleer aan die anderkant.

AANBIEDING:

Wit, polipropileen securitainers met wit, LDPE (laedigtheidpoliëtileen) deksels met 10, 20, 100, 200 en 250 tablette en wit, HDPE (hoëdigtheidpolietileen) houers met wit, HDPE skroefdeksels met 200 tablette en PVC/Aluminiumfoelie stulpverpakkings van 10, 20, 50, 100 & 200 tablette.

BERGINGSAANWYSINGS:

Bêre benede 25 ºC en beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

27/5.7.2/0386

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

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