SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ADCO-CYCLIZINE 50 mg, TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Cyclizine hydrochloride 50 mg

Contains sugar: Lactose 19,5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ADCO-CYCLIZINE 50 mg is indicated in the prevention and treatment of nausea and vomiting including motion sickness, nausea and vomiting caused by narcotic analgesics and vomiting associated with radiotherapy and cancer chemotherapy.

ADCO-CYCLIZINE 50 mg may be of value in the symptomatic management of vertigo and labyrinth disorders (Ménière syndrome).

4.2 Posology and method of administration

Posology:

Adults and children over 12 years: 1 tablet three times a day, not to exceed 200 mg daily.

For the prevention of motion sickness, one tablet is taken 20 to 30 minutes before departure. This dose may be repeated three times daily if necessary.

Special populations:

Elderly patients:

There have been no specific studies of ADCO-CYCLIZINE 50 mg in the elderly.

Paediatric population

Children 6 to 12 years: ½ tablet three times a day, not to exceed 75 mg daily.

The dosage for children aged 6 to 12 years is half the adult dosage.

Method of administration

ADCO-CYCLIZINE 50 mg is for oral administration.

4.3 Contraindications

- ADCO-CYCLIZINE 50 mg is contraindicated in individuals who have previously reacted adversely to cyclizine.
- ADCO-CYCLIZINE 50 mg is contraindicated in pregnancy and lactation.
- Antihistamines are contraindicated in acute asthma attacks due to the anticholinergic effects of this class of medicines.
- ADCO-CYCLIZINE 50 mg is contraindicated in the presence of acute alcohol intoxication. The anti-emetic properties of cyclizine may increase the toxicity of alcohol.

4.4 Special warnings and precautions for use

Paradoxical central nervous system stimulation may occur, especially in children, with insomnia, nervousness, tachycardia, tremors and convulsions.

Fixed drug eruptions, generalised chorea and hypersensitivity hepatitis have been reported after oral administration.

Antihistamines may precipitate epileptiform seizures in patients with focal lesions of the cerebral cortex. Elderly patients may be more susceptible to the central nervous system effects and hypotensive effects of cyclizine.

Antihistamines may supress positive skin test results.

There have been no studies of ADCO-CYCLIZINE 50 mg tablets in patients with hepatic and/or renal dysfunction.

Cholestatic jaundice has been reported.

ADCO-CYCLIZINE 50 mg tablets have anticholinergic properties and should be used with care in conditions such as glaucoma and prostatic hypertrophy, urinary retention, obstructive disease of the gastrointestinal tract, hepatic disease, phaeochromocytoma, hypertension, epilepsy.

ADCO-CYCLIZINE 50 mg should be used with caution in patients with severe heart failure or acute myocardial infarction. In such patients, cyclizine may cause a fall in cardiac output associated with increases in heart rate, mean arterial pressure and pulmonary wedge pressure.

ADCO-CYCLIZINE 50 mg should be avoided in porphyria.

There have been reports of abuse of cyclizine, either oral or intravenous, for its euphoric or hallucinatory effects. The concomitant misuse of Cyclizine Hydrochloride with large amounts of alcohol is particularly dangerous, since the antiemetic effect of cyclizine may increase the toxicity of alcohol (see also sections 4.3 and 4.5).

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 such as aminoglycoside antibiotics and may affect the metabolism of drugs in the liver.

Excipient warnings:

ADCO-CYCLIZINE 50 mg tablets contain lactose, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

ADCO-CYCLIZINE 50 mg tablets may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilizers.

The side effects of anticholinergic medicines such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of antihistamines.

Monoamine oxidase inhibitors may enhance the anti-muscarinic effects of antihistamines.

ADCO-CYCLIZINE 50 mg tablets enhances the soporific effect of pethidine.

Cyclizine Hydrochloride may counteract the haemodynamic benefits of opioid analgesics.

Cyclizine Hydrochloride may mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibacterials.

4.6 Fertility, pregnancy and lactation

The safety of ADCO-CYCLIZINE 50 mg during pregnancy and lactation has not been established.

Pregnancy:

ADCO-CYCLIZINE 50 mg should not be used in pregnancy (see section 4.3).

Breast-feeding:

ADCO-CYCLIZINE 50 mg should not be used during breastfeeding (see section 4.3).

Cyclizine is excreted in human milk; however, the amount has not been quantified

Fertility:

No data available.

4.7 Effects on ability to drive and use machines

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.

4.8 Undesirable effects

Tabulated summary of adverse reactions

MedDRA System Organ Class	**Frequency**	**Side effects**
Blood and lymphatic system disorders	*Frequency unknown:*	Agranulocytosis, leucopenia, haemolytic anaemia, hrombocytopenia.
Cardiac disorders	*Frequency unknown:*	Tachycardia, tightness of the chest and tingling, heaviness and weakness of the hands, palpitations, dysrhythmias.
Ear and labyrinth disorder	*Frequency unknown:*	Tinnitus.
Eye disorders	*Frequency unknown:*	Blurred vision, oculogyric crisis.
Gastrointestinal disorders	*Frequency unknown:*	Dryness of the mouth, nose and throat, constipation increased gastric reflux. Nausea, vomiting, diarrhoea, constipation and epigastric/ stomach pain, Increase/Loss of appetite.
General disorders and administration site conditions	*Frequency unknown:*	Asthenia.
Hepatobiliary disorders	*Frequency unknown:*	Hepatic dysfunction, hypersensitivity hepatitis, cholestatic jaundice and cholestatic hepatitis have occurred in association with cyclizine.
Immune system disorders	*Frequency unknown:*	Hypersensitivity reactions, including anaphylaxis have occurred.
Musculoskeletal and connective tissue disorders	*Frequency unknown:*	Twitching, muscle spasms.
Nervous system disorders	*Frequency unknown:*	Effects on the central nervous system have been reported with cyclizine. These include somnolence, drowsiness, lassitude, muscle weakness, incoordination, headache, anorexia, dystonia, dyskinesia, extrapyramidal motor

		disturbances, restless leg syndrome, tremor, convulsions, dizziness, decreased consciousness, transient speech disorders, paraesthesia and generalised chorea.
Psychiatric disorders	*Frequency unknown:*	Disorientation, elation or depression, restlessness, nervousness, nightmares, irritability, euphoria, insomnia and auditory and visual hallucinations have been reported, particularly when dosage recommendations have been exceeded.
Renal and urinary disorders	*Frequency unknown:*	Urinary retention, dysuria, difficulty in micturition.
Respiratory, thoracic and mediastinal disorders	*Frequency unknown:*	Bronchospasm, apnoea.
Skin and subcutaneous tissue disorders	*Frequency unknown:*	Urticaria, drug rash, angioedema, allergic skin reactions, fixed drug eruption, photosensitivity.
Vascular disorders	*Frequency unknown:*	Hypertension, hypotension.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Symptoms of acute toxicity arise from peripheral anticholinergic effects and effects on the central nervous system.

Peripheral anticholinergic symptoms include dry mouth, nose and throat, blurred vision, tachycardia and urinary retention.

Overdosage may be fatal, especially in infants and children in whom the main symptoms are central nervous system stimulation and antimuscarinic effects including ataxia, drowsiness, dizziness, incoordination, weakness, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, facial flushing, hyperpyrexia and respiratory depression.

Hypotension may also occur.

Treatment of overdosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 5.7.2. Anti-emetics and antivertigo preparations

ATC Code: R06AE03

Mechanism of action:

Cyclizine is an histamine H_1 receptor antagonist of the piperazine class and is useful in the treatment of vertigo.

It possesses anticholinergic and anti-emetic properties.

The exact mechanism by which cyclizine can prevent or supress both nausea and vomiting from various causes is unknown. Cyclizine increases lower oesophageal sphincter tone and reduces the sensitivity of the labyrinthine apparatus. It may inhibit the part of the midbrain known collectively as the emetic centre.

Pharmacodynamic effects

Cyclizine produces its antiemetic effect within two hours and lasts approximately four hours.

5.2 Pharmacokinetic properties

Absorption

H1-blockers are well absorbed from the GI tract. Following oral administration effects develop within 30 minutes, are maximal within 1-2 hours and last, for cyclizine, for 4-6 hours.

Distribution

In healthy adult volunteers the administration of a single oral dose of 50 mg cyclizine resulted in a peak plasma concentration of approximately 70 ng/mL occurring at about two hours after drug administration. The plasma elimination half-life was approximately 20 hours.

Biotransformation:

The N-demethylated derivative, norcyclizine, has been identified as a metabolite of cyclizine. Norcyclizine has a little antihistaminic (H1) activity compared to cyclizine and has a plasma elimination half-life of approximately 20 hours.

Elimination

After a single dose of 50 mg cyclizine given to a single adult male volunteer, urine collected over the following 24 hours contained less than 1% of the total dose administered.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose,

Magnesium stearate,

Maize starch,

Pregelatinised maize starch,

Sodium starch glycollate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK/ 232625

8. REGISTRATION NUMBER

27/5.7.2/0386

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 July 1993

10. DATE OF REVISION OF THE TEXT

16 March 2026

Namibia		
	Product name	**Registration number**
	Adco-Cyclizine 50 mg	05/5.7.2/0119