

## MEDAZINE SYRUP

### SCHEDULING STATUS:

**S2**

### 1 NAME OF THE MEDICINE

**MEDAZINE S** (12,5 mg Syrup)

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Cyclizine hydrochloride      12,5 mg

Preservatives:

Methyl hydroxybenzoate      0,12 % *m/v*

Propyl hydroxybenzoate      0,02 % *m/v*

Contains alcohol              6 % *v/v*

Contains sorbitol 70 %

Contains sugar: (1,25 mg liquid glucose and 0,5 mg sucrose per 5 mL).

Contains sweetener (saccharine sodium 2,5 mg per 5 mL)

For full list of excipients, see **section 6.1**

### 3 PHARMACEUTICAL FORM

Syrup

Clear yellow syrup with a naartjie flavour.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

MEDAZINE S is indicated for the prevention and treatment of nausea and vomiting, particularly motion sickness and labyrinthine disorders (Meniere's Syndrome).

### **4.2 Posology and method of administration**

#### **Posology**

To prevent motion sickness MEDAZINE S Syrup should be taken about half an hour before the journey.

Children 6 to 12 years: 10 mL (2 medicine measures), may be repeated up to three times daily.

Children 2 to 5 years: 5 mL (1 medicine measure), may be repeated up to three times daily.

#### **Special populations**

##### **Elderly patients**

There have been no specific studies of MEDAZINE S in the elderly.

#### **Method of administration**

MEDAZINE S is for oral administration.

### **4.3 Contraindications**

MEDAZINE S is contraindicated in:

- Individuals who have previously reacted adversely to cyclizine or to any of the inactive ingredients of MEDAZINE S, listed in **section 6.1**.

- The safety of MEDAZINE S during pregnancy and lactation has not been established.
- Antihistamines are contraindicated in acute asthma attacks due to the anticholinergic effects of this class of medicines.
- Anticholinergics should not be used in conditions such as narrow angle glaucoma, urinary retention, prostatic hypertrophy, emphysema, chronic pulmonary disease, shortness of breath, and difficulty in breathing, unless directed by a medical practitioner.

#### **4.4 Special warnings and precautions for use**

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.

Antihistamines may precipitate epileptiform seizures in patients with focal lesions of the cerebral cortex.

Antihistamines may suppress positive skin test results.

MEDAZINE S Syrup may affect the metabolism of drugs in the liver.

#### **Paediatric population**

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

#### **4.5 Interaction with other medicines and other forms of interaction**

Patients are warned that MEDAZINE S Syrup may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilizers.

Since MEDAZINE S 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 medicines such as atropine and tricyclic antidepressants may be enhanced by the concomitant administration of MEDAZINE S. Syrup.

MEDAZINE S may mask the warning symptoms of damage caused by ototoxic medicines.

Restlessness, dizziness and tachycardia may occur if atropine and MEDAZINE S Syrup are used together.

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

MEDAZINE S enhances the soporific effect of pethidine.

#### **4.6 Fertility, pregnancy and lactation**

The safety of MEDAZINE S during pregnancy and lactation has not been established.

#### **4.7 Effects on ability to drive and use machines**

MEDAZINE S may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants. 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**

##### **Blood and lymphatic system disorders:**

The following side effects have been reported and frequencies are unknown:

Blood disorders, including agranulocytosis and haemolytic anaemia.

##### **Immune system disorders:**

The following side effects have been reported and frequencies are unknown:

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

**Psychiatric disorders:**

The following side effects have been reported and frequencies are unknown: Drowsiness, inability to concentrate, lassitude, dizziness, incoordination, headache, elation or depression, irritability, nightmares, and tingling, heaviness and weakness of the hands as well as generalised chorea. In children MEDAZINE S may have the same effect as a central stimulant.

**Eye disorders:**

The following side effects have been reported and frequencies are unknown: Blurred vision.

**Ear and labyrinth disorders:**

The following side effects have been reported and frequencies are unknown: Tinnitus.

**Vascular disorders:**

The following side effects have been reported and frequencies are unknown: Hypotension.

**Respiratory, thoracic and mediastinal disorders:**

The following side effects have been reported and frequencies are unknown: Tightness of the chest.

**Gastrointestinal disorders:**

The following side effects have been reported and frequencies are unknown: Dryness of mouth, nose and throat, diarrhoea or constipation, epigastric pain, and anorexia.

**Hepato-biliary disorders:**

The following side effects have been reported and frequencies are unknown: Cholestatic jaundice has been reported.

**Skin and subcutaneous tissue disorders:**

The following side effects have been reported and frequencies are unknown: Fixed drug eruptions.

**Musculoskeletal and connective tissue disorders:**

The following side effects have been reported and frequencies are unknown: Muscular weakness.

**Renal and urinary disorders:**

The following side effects have been reported and frequencies are unknown: Difficulty in micturition.

**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 the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8> and to Cipla Medpro (Pty) Ltd at [drugsafetysa@cipla.com](mailto:drugsafetysa@cipla.com) or telephone 080 222 6662 (toll free).

#### **4.9 Overdose**

Symptoms of acute overdosage arise from effects of the preparation on the central nervous system and include drowsiness, dizziness, incoordination, weakness, convulsions, hyperpyrexia and respiratory depression. Agitation, ataxia and hallucinations may occur.

Treatment is symptomatic and supportive.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

##### **Pharmacotherapeutic group**

A 5.7.2 Anti-emetics and antivertigo preparations.

##### **Mechanism of action**

Cyclizine is a histamine H<sub>1</sub> 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 suppress 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.

#### **5.2 Pharmacokinetic properties**

The N-demethylated derivative, norcyclizine, has been identified as a metabolite of cyclizine.

Norcyclizine has a little antihistaminic (H<sub>1</sub>) activity compared to cyclizine and has a plasma elimination half-life of approximately 20 hours.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Liquid glucose,

Purified water,

Methyl Hydroxybenzoate,

Propyl Hydroxybenzoate,

Saccharine sodium,

Citric acid monohydrate,

Sodium citrate,

Yellow colour F1523 (Quinolene Yellow CI No. 47005 & Sunset Yellow CI No. 15958),

Naartjie flavour,

Sucrose,

Alcohol 96 %,

Sorbitol 70 % .

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

2 years

### **6.4 Special precautions for storage**

Store at or below 25 °C

## **6.5 Nature and contents of container**

MEDAZINE S is packed in a round amber glass bottles containing 50 mL, 100 mL, 200 mL and 500 mL syrup and amber PET bottles containing 50 mL syrup, packed in unit carton.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

No special requirements

## **7 HOLDER OF CERTIFICATE OF REGISTRATION**

### **CIPLA MEDPRO (PTY) LTD.**

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

## **8 REGISTRATION NUMBER(S)**

27/5.7.2/0204

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

16 March 1993

## **10 DATE OF REVISION OF THE TEXT**

20 February 2023

Namibia: NS1 11/5.7.2/0061