PROFESSIONAL INFORMATION FOR

CIPLA-ACTIN

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

CIPLA-ACTIN 4mg (tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains cyproheptadine hydrochloride equivalent to cyproheptadine hydrochloride (anhydrous) 4 mg.

Excipient with known effect:

Contains sugar (lactose monohydrate 96,87 mg per tablet).

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

3 PHARMACEUTICAL FORM

Tablets.

White circular tablets with flat bevelled edges with 'CTN' engraved on one side and a central break-line on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

CIPLA-ACTIN is used in the symptomatic treatment of seasonal and perennial rhinitis.

CIPLA-ACTIN is also indicated for the symptomatic relief of pruritus.

4.2 Posology and method of administration

Posology

Dosage must be determined on an individual basis. The effect of a single dose usually lasts for four to six hours. For continuous effective relief, the daily requirement should be given in divided doses, usually three times a day, or as often as necessary, to provide continuous relief.

Adults:

The therapeutic range is from 4 mg to 20 mg per day. The majority of patients require 12 mg to 16 mg a day. It is suggested that the dosage be initiated with 4 mg (1 tablet) three times a day and adjusted according to the weight and response of the patient.

Children (7 to 14 years):

The usual dosage is 4 mg (1 tablet) 2 or 3 times a day. The dosage may be adjusted according to size and response of the child. Should an additional dose be required, it should preferably be taken at bedtime. The dosage must not exceed 16 mg per day.

Children (2 to 6 years):

The suggested dosage is 2 mg (1/2 tablet) 2 or 3 times a day. The dosage may be adjusted according to size and response of the child. Should an additional dose be required, it should preferably be taken at bedtime. The daily dosage should not exceed 8 mg.

Method of administration

For oral administration.

4.3 Contraindications

CIPLA-ACTIN is contraindicated in:

- Patients with known hypersensitivity to cyproheptadine hydrochloride and other medicines of similar chemical structure or to any of the excipients of CIPLA-ACTIN (see **section 6.1**)
- patients with closed angle glaucoma
- patients with a predisposition to urinary retention or bladder neck obstruction
- patients with symptomatic prostatic hypertrophy
- patients on monoamine oxidase inhibitor therapy
- patients with stenosing peptic ulcer
- pyloroduodenal obstruction
- the elderly, debilitated patients
- breastfeeding mothers
- patients undergoing therapy for an acute asthmatic attack.

4.4 Special warnings and precautions for use

Antihistamines, such as CIPLA-ACTIN, should not be used to treat lower respiratory tract symptoms, including acute asthma.

The safety and efficacy of CIPLA-ACTIN is not established in children under 2 years old.

Overdosage of antihistamines, such as CIPLA-ACTIN, particularly in children, may produce hallucinations, central nervous system depression, convulsions, respiratory and cardiac arrest, and death.

Mental alertness

CIPLA-ACTIN may diminish mental alertness; conversely, it may occasionally produce excitation, particularly in the young child.

Patients should be warned against engaging in activities requiring motor co-ordination and mental alertness, such as driving a car or operating machinery (see **section 4.7**).

Elderly patients

Dizziness, sedation and hypotension is more likely to occur in elderly patients.

Blood Dyscrasias

Prolonged therapy with CIPLA-ACTIN may cause blood dyscrasias.

Other

Due to the atropine-like action of CIPLA-ACTIN, it should be used with caution in patients with a history of bronchial asthma, hyperthyroidism, increased intra-ocular pressure, cardiovascular disease and hypertension.

Paediatric population

Safety and efficacy in children below the age of two years have not been established (see **section 4.3**).

Lactose monohydrate

CIPLA-ACTIN contains lactose monohydrate.

Patients with the rare hereditary conditions of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take CIPLA-ACTIN.

4.5 Interaction with other medicines and other forms of interaction

Monoamine oxidase inhibitors

Monoamine oxidase (MAO) inhibitors may prolong and intensify the anticholinergic effects of CIPLA-ACTIN (see **section 4.3**).

Central Nervous System (CNS) depressants

CIPLA-ACTIN may have additive effects when combined with alcohol and other CNS depressants, e.g. hypnotics, sedatives, tranquillizers and anxiolytics.

CIPLA-ACTIN may interfere with serotonin-enhancing antidepressant medicines, including selective serotonin re-uptake inhibitors (SSRIs), due to its anti-serotonin activity. This may result in possible recurrence of depression and related symptoms.

When evaluating a urine or serum drug screen, a false positive result for tricyclic anti-depressant medicines may be obtained when using CIPLA-ACTIN.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and/or efficacy in pregnancy has not been established (see **section 4.3**).

Breastfeeding

CIPLA-ACTIN is contraindicated in breastfeeding mothers (see **section 4.3**).

4.7 Effects on ability to drive and use machines

CIPLA-ACTIN may lead to drowsiness and impaired concentration that may be aggravated

by the 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 could lead to accidents.

4.8 Undesirable effects

a. Summary of the safety profile

The side effects that present frequently are drowsiness and somnolence. The drowsiness effect may subside after the first three or four days of continuous administration.

b. Tabulated list of adverse reactions

The following adverse reactions have been reported with the use of CIPLA-ACTIN.

MedDRA system organ class	**Frequency**	**Adverse reactions**
Blood and lymphatic system disorders	Frequency unknown	Haemolytic anaemia, agranulocytosis, leukopenia and thrombocytopenia
Immune system disorders	Frequency unknown	Allergic manifestation of rash and oedema, anaphylactic shock
Metabolism and nutrition disorders	Frequency unknown	Anorexia, increased appetite, weight gain
Psychiatric disorders	Frequency unknown	Confusion, restlessness, excitation, irritability, nervousness, insomnia, aggressive behaviour, hallucinations, hysteria and euphoria

MedDRA system organ class	**Frequency**	**Adverse reactions**
Nervous system disorders	Frequency unknown	Sedation, sleepiness (often transient), disturbed coordination, dizziness, tremor, paraesthesiae, convulsions, neuritis, faintness and headache
Eye disorders	Frequency unknown	Blurred vision, diplopia
Ear and labyrinth disorders	Frequency unknown	Tinnitus, acute labyrinthitis and vertigo
Cardiac disorders	Frequency unknown	Tachycardia, palpitations, extrasystoles
Vascular disorders	Frequency unknown	Hypotension
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Thickening of bronchial secretions, dryness of nose and throat, tightness of chest and wheezing, nasal stuffiness, epistaxis
Gastrointestinal disorders	Frequency unknown	Dryness of the mouth, epigastric distress, nausea and vomiting, diarrhoea, and constipation
Hepatobiliary disorders	Frequency unknown	Jaundice, cholestasis, hepatic failure, hepatitis, hepatic function abnormality
Skin and subcutaneous tissue	Frequency unknown	Photosensitivity, excessive perspiration and urticaria

MedDRA system organ class	Frequency	Adverse reactions
disorders		
Renal and urinary disorders	Frequency unknown	Frequency of micturition, difficult micturition, urinary retention
Reproductive system and breast disorders	Frequency unknown	Early menses
General disorders and administration site conditions	Frequency unknown	Fatigue, rigors

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 drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

4.9 Overdose

Symptoms

Signs and symptoms of CIPLA-ACTIN overdosage may vary from hallucinations and central nervous system depression or stimulation to convulsions, respiratory and cardiac arrest and death, especially in children (see **section 4.3**). Atropine-like effects (dry mouth, fixed dilated pupils, flushing, etc), as well as gastrointestinal symptoms may occur.

Treatment

If overdosage occurs, the patient should be monitored, and standard supportive treatment applied as required. If vomiting has not occurred spontaneously, vomiting should be induced if the patient is conscious. Stimulants should not be used. Hypotension may be treated with vasopressors.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 5.7.1 Antihistaminics.

Pharmacotherapeutic group: Other antihistamines for systemic use

ATC code: R06AX02

Mechanism of action

Cyproheptadine hydrochloride, a piperidine derivative, is a sedating antihistamine with antimuscarinic, serotonin-antagonist and calcium-channel blocking actions.

5.2 Pharmacokinetic properties

The principal metabolite found in the urine is the quaternary ammonium glucuronide conjugate of cyproheptadine. 2 % to 20 % is excreted in the faeces, of which 34 % (5,7 % of the dose) is unchanged medicine. At least 40 % is excreted in the urine.

Elimination is diminished in renal insufficiency.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic calcium phosphate

Lactose monohydrate

Maize starch

Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dry place at or below 25 °C, protect from light.

6.5 Nature and contents of container

Each carton contains colourless, transparent PVC and aluminium foil combipack blister strips of 10 tablets, in packs of 30.

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)

36/5.7.1/0072

Namibia: NS1 10/5.7.1/0577

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 25 July 2003

Latest renewal: Not applicable.

10 DATE OF REVISION OF THE TEXT

05 June 2026.