***Enquiries*:** variations@sahpra.org.za

CLINICAL APPROVAL LETTER: POST REGISTRATION APPLICATIONS

Clinical approval date	05 June 2026
Applicant's cover letter date	26 February 2026
Applicant	Cipla
Proprietary name(s) (including duplicates)	CIPLA-ACTIN
API(s)	Cyproheptadine hydrochloride
Registration number(s)	36/5.7.1/0072
Sequence no	0005

Dear Sir/Madam,

Kindly be informed that the Authority has completed the evaluation of the above-mentioned Professional Information (PI) and Patient Information Leaflet (PIL) variation application.

1. The amendments to the PI and PIL are approved.
2. The PI and PIL be accepted as the currently approved PI and PIL
3. The date of revision reflected on this PI and PIL should be**:05 June 2026**
4. The final dated version of the above PI and PIL must be submitted via docubridge in a closing sequence using the Sequence Type "Closing sequence" and Sequence Description "Approved " updated PI and PIL within 10 working days.
5. The approved PI and PIL must be uploaded into the SAHPRA repository within 10 working days.

Note to applicant: Amendments to any quality aspects of the medicine within the PI and PIL are subject to P&A unit approval and may only be implemented in the PI if approved by the P&A unit.

Yours Faithfully,

L.DHLAMINI

MANAGER: CLINICAL POST-REGISTRATION UNIT

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
Nervous system disorders	Frequency unknown	Sedation, sleepiness (often transient), disturbed coordination, dizziness, tremor, paraesthesiae, convulsions, neuritis, faintness and headache

MedDRA system organ class	**Frequency**	**Adverse reactions**
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 disorders	Frequency unknown	Photosensitivity, excessive perspiration and urticaria
Renal and urinary disorders	Frequency unknown	Frequency of micturition, difficult micturition, urinary retention
Reproductive system	Frequency	Early menses

MedDRA system organ class	Frequency	Adverse reactions
and breast disorders	unknown	
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

To be allocated.

PATIENT INFORMATION LEAFLET FOR

CIPLA-ACTIN

SCHEDULING STATUS:

S2

CIPLA-ACTIN 4 mg (tablets)

Cyproheptadine hydrochloride (anhydrous)

Contains sugar: lactose monohydrate 96,87 mg per tablet

Read all of this leaflet carefully because it contains important information for you.

CIPLA-ACTIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CIPLA-ACTIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CIPLA-ACTIN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a number of days.

What is in this leaflet

1. What CIPLA-ACTIN is and what it is used for

CIPLA-ACTIN contains cyproheptadine hydrochloride, which belongs to a group of medicines known as sedating antihistamines.

CIPLA-ACTIN is used in the symptomatic treatment of seasonal and perennial rhinitis (sneezing, runny nose). CIPLA-ACTIN is also indicated for the symptomatic relief of pruritus (itching).

2. What you need to know before you take CIPLA-ACTIN

Do not take CIPLA-ACTIN if you:

- are allergic (hypersensitive) to cyproheptadine hydrochloride and other medicines of similar chemical structure or any other ingredients of CIPLA-ACTIN (listed in **section 6**)
- suffer from an increased pressure in the eye (closed angle glaucoma)
- are finding it difficult to empty your bladder
- have an enlarged prostrate
- are on monoamine oxidase inhibitor therapy, such as moclobemide for depression
- have a stomach ulcer
- have an obstruction of the small intestine
- are weak, frail and older than 65 years
- are receiving treatment for an asthmatic attack or lower respiratory tract symptoms
- are younger than 2 years old
- are pregnant or breastfeeding your baby (see "**Pregnancy, breastfeeding and fertility**").

Warnings and precautions

Take special care with CIPLA-ACTIN if you:

- suffer from high blood pressure (hypertension)
- suffer from asthma
- have ever been told that you have high pressure inside your eye (high intra-ocular pressure)
- suffer from diseases of the heart or blood vessels (cardiovascular diseases)
- suffer from an overactive thyroid (hyperthyroidism).

CIPLA-ACTIN should not be used to treat asthma. Overdosage of CIPLA-ACTIN in children may cause hallucinations (seeing or hearing things that are not real), convulsions, sleepiness, cardiac arrest and death (see "**Do not take CIPLA-ACTIN**").
Occasionally, CIPLA-ACTIN may cause excitation/hyperactivity in young children.

Patients should be warned not to do activities that need coordination and full attention—like driving or using machines—because the medicine might make them feel drowsy or less alert (See also section "**Driving and using machines"**).

Dizziness, sleepiness and low blood pressure is more likely to occur in elderly.
Prolonged treatment with CIPLA-ACTIN may cause disorders of blood cells.

Other medicines and CIPLA-ACTIN

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Please inform your doctor if you are taking any of the following medicines:

- monoamine oxidase inhibitors (moclobemide and tranylcypromine) for depression as

it may prolong and intensify the effects of CIPLA-ACTIN (see "**Do not take CIPLA-ACTIN**")

- CIPLA-ACTIN may increase effects of hypnotics, sedatives, tranquillizers and anxiolytics as it may increase the effect of CIPLA-ACTIN
- Selective serotonin re-uptake inhibitors (SSRIs) (e.g. paroxetine, citalopram). It may result in depression and related symptoms recurring
- CIPLA-ACTIN may cause a false positive result for tricyclic anti-depressant medicines (e.g. amitriptyline hydrochloride, clomipramine hydrochloride) in urine or blood tests.

CIPLA-ACTIN with food, drink and alcohol

Do not take CIPLA-ACTIN with alcohol, as your ability to drive or operate machinery may be impaired.

Pregnancy, breastfeeding and fertility

Do not take CIPLA-ACTIN while you are pregnant or breastfeeding your baby (see "**Do not take CIPLA-ACTIN**").

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CIPLA-ACTIN.

Driving and using machines

It is not always possible to predict to what extent CIPLA-ACTIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CIPLA-ACTIN affects them.

CIPLA-ACTIN may cause you to feel dizzy and light-headed and may therefore affect your ability to drive or operate machinery. Do not drive or operate machinery until you know how CIPLA-ACTIN affects you.

CIPLA-ACTIN contains lactose

Do not take CIPLA-ACTIN if you have been told by your doctor that you have intolerance to some sugars. Contact your doctor before taking CIPLA-ACTIN.

3. How to take CIPLA-ACTIN

Do not share medicines prescribed for you with any other person.

Always take CIPLA-ACTIN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

CIPLA-ACTIN should be taken orally. The dosage should be determined on an individual basis. The daily dose should be taken in divided doses, usually three times a day, or as prescribed by your doctor to provide continuous relief.

Adults:

You may start the treatment with 4 mg (1 tablet) three times a day and adjust the dose according to your weight and response to the medicine. The majority of patients require 3 to 4 tablets per day. Do not take more than 20 mg (5 tablets) per day.

Children (7 to 14 years):

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

Children (2 to 6 years):

The suggested dosage is 2 mg (a half tablet) 2 or 3 times a day. Your doctor will adjust the dose according to your size and response to the medicine. Should your child require an additional dose, it should preferably be taken at bedtime. The dosage must not exceed 8 mg (2 tablets) per day.

If you take more CIPLA-ACTIN than you should

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side effects listed below (see section "**Possible side-effects**").

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or Poison Centre.

If you forget to take CIPLA-ACTIN

Do not take a double dose to compensate for the forgotten individual dose.

4. Possible side effects

CIPLA-ACTIN can have side effects.

Not all side effects reported for CIPLA-ACTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLA-ACTIN, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking CIPLA-ACTIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing and breathing
- rash, hives

- yellowing of skin and eyes also called jaundice
- pain in the liver area, dark urine and tiredness which may be symptoms of liver problems (hepatitis, hepatic failure).

These are all very serious side effects. If you have them, you have had a serious allergic reaction to CIPLA-ACTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- pins and needles
- hearing and seeing things that are not real (hallucinations)
- difficulty urinating, kidney pain
- epileptic seizure
- ringing in the ears, inner ear infection, spinning and moving surroundings
- bruising of skin, unusual bleeding, pinpoint red spots on the skin, pale skin, unusual tiredness or weakness, fever or chills as these symptoms may be due to abnormal blood cell and platelet counts
- fast heartbeat, pounding heartbeat, irregular heartbeat.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- sleepiness or drowsiness (the drowsiness side effect might get less after 3 to 4 days of use).

Side effects with unknown frequency:

- loss of appetite

- weight gain
- increased appetite
- confusion
- restlessness
- excitation
- irritability
- nervousness
- insomnia
- aggressive behaviour, hysteria, euphoria
- sedation, dizziness, disturbed coordination
- twitching of body parts (tremor)
- faintness and headache
- inability to see fine details (blurred vision)
- low blood pressure causing you to feel dizzy, especially when standing up
- double vision
- thick mucus
- dryness of nose and throat, coughing due to thick mucus
- tightness of chest
- wheezing
- nasal stuffiness
- nose bleeds
- stomach pain, dry mouth
- nausea and vomiting
- diarrhoea (loose stools)
- constipation
- rash on skin exposed to the sun

- excessive sweating
- early menses, fatigue, rigor.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects 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 e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CIPLA-ACTIN.

5. How to store CIPLA-ACTIN

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

Store all medicines out of reach of children.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CIPLA-ACTIN contains

The active ingredient in CIPLA-ACTIN is cyproheptadine hydrochloride. Each tablet contains cyproheptadine hydrochloride equivalent to cyproheptadine hydrochloride (anhydrous) 4 mg. The other ingredients are dibasic calcium phosphate, magnesium stearate, maize starch and lactose monohydrate.

What CIPLA-ACTIN looks like and contents of the pack

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

Contents of the pack:

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

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer care: 080 2226662

This leaflet was last revised in

First authorisation: 25 July 2003.

Latest renewal: Not applicable.

Revision: To be allocated.

Registration number(s)

36/5.7.1/0072

Namibia: NS1 10/5.7.1/0577

Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.