PROFESSIONAL INFORMATION FOR

OXYMETAZOLINE CIPLA 0,025 / 0,05 (Metered nasal spray)

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

OXYMETAZOLINE CIPLA 0,025 0,25 mg/1 mL, Metered nasal spray

OXYMETAZOLINE CIPLA 0,05 0,5 mg/1 mL, Metered nasal spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

OXYMETAZOLINE CIPLA 0,025: Each 1 mL of solution contains 0,25 mg oxymetazoline hydrochloride (0,025 % *m/v*), and 0,01 % *m/v* benzalkonium chloride as preservative.

Contains sugar: sorbitol 3,5 mg/1 mL.

OXYMETAZOLINE CIPLA 0,05: Each 1 mL of solution contains 0,5 mg oxymetazoline hydrochloride (0,05 % *m/v*), and 0,01 % *m/v* benzalkonium chloride as preservative.

Contains sugar: sorbitol 3,5 mg/1 mL.

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

3. PHARMACEUTICAL FORM

Metered nasal spray.

OXYMETAZOLINE CIPLA 0,025: Clear, colourless solution

OXYMETAZOLINE CIPLA 0,05: Clear, colourless solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OXYMETAZOLINE CIPLA is indicated:

- For the relief of nasal congestion due to:
  - The common cold (acute rhinitis).
  - Sinusitis.
  - Allergic rhinitis.
  - Hay-fever.
- As adjunctive treatment in otitis media (middle ear infection).

4.2 Posology and method of administration

Posology

OXYMETAZOLINE CIPLA 0,05 metered spray is indicated for adults and children over 6 years.

OXYMETAZOLINE CIPLA 0,025 metered spray is indicated for children up to the age of 6 years.

OXYMETAZOLINE CIPLA should not be used for a period longer than five days (see **section 4.4**).

Do not exceed the recommended dosage. If symptoms persist, consult a health care provider.

Dosage:

OXYMETAZOLINE CIPLA 0,05:

Adults: 1 - 2 sprays into each nostril 2 – 3 times a day

Paediatric population

OXYMETAZOLINE CIPLA 0,05:

Children over 6 years: 1 spray into each nostril 2 - 3 times a day.

OXYMETAZOLINE CIPLA 0,05 is contraindicated in children below the age of 6 years (see **section 4.3**).

The single dose given for OXYMETAZOLINE CIPLA 0,05 must not be administered more than 3 times a day.

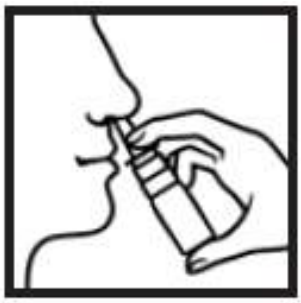
OXYMETAZOLINE CIPLA 0,025:

Children up to the age of 6 years: 2 to 3 sprays into each nostril 2 – 3 times a day.

Method of administration

Metered nasal spray for nasal use.

For best results keep both the head and spray bottle in an upright position. Remove the cap by pulling and insert the nozzle of the spray loosely into the nostril with the middle and forefinger around the bottom of the nozzle and the thumb on the base of the bottle. Depress the spray mechanism (as shown in the diagram) thus producing a fine mist. Sniff in to ensure an even distribution of the spray. Withdraw from nostril and release the spray mechanism. Repeat for the other nostril.



Prevention of contamination:

- Patients should be instructed to wipe the tip of the applicator with a clean, damp tissue and replace the cap directly after use.
- Each bottle of OXYMETAZOLINE CIPLA should not be used by more than one patient.

4.3 Contraindications

OXYMETAZOLINE CIPLA is contraindicated in:

- Patients with known hypersensitivity to oxymetazoline hydrochloride, benzalkonium chloride, or to any of the other ingredients in OXYMETAZOLINE CIPLA (see **section 6.1**).
- Patients with rhinitis sicca (inflammation of the skin and mucosa of the nasal vestibule and encrustation).
- Patients who underwent trans-sphenoidal hypophysectomy or nasal surgery exposing the dura mater.
- Patients concomitantly using other sympathomimetic decongestants.
- Phaeochromocytoma.

OXYMETAZOLINE CIPLA 0,05 is contraindicated in children below six years of age.

OXYMETAZOLINE CIPLA is considered unsafe in porphyria and has been associated with acute attacks of porphyria.

4.4 Special warnings and precautions for use

In the following cases, OXYMETAZOLINE CIPLA may only be used after carefully weighing the risk-to-benefit ratio:

- Patients treated with monoamine oxidase inhibitors or, have taken MAOIs in the previous two weeks or, tricyclic antidepressants, and other medicines such as stated in **section 4.5**.
- Medicines potentially increasing blood pressure.
- Increased intraocular pressure, especially narrow-angle glaucoma.
- Severe cardiovascular diseases (e.g. coronary heart disease, angina, hypertension, cardiac asthma).
- Metabolic disorders (e.g. hyperthyroidism, diabetes mellitus).
- Hyperplasia of the prostate.
- Hepatic disorders.
- Renal disorders.
- Occlusive vascular disease.
- **Do not exceed the recommended dose.**
- If symptoms worsen or do not improve after 3 days, a medical practitioner should re-evaluate the clinical situation.
- OXYMETAZOLINE CIPLA should be used for a maximum of 5 consecutive days to avoid a rebound-effect and medicine-induced rhinitis.

Long-term use and overdosage of OXYMETAZOLINE CIPLA should be avoided.

The efficacy OXYMETAZOLINE CIPLA may be reduced (tachyphylaxis) with long-term use or overdose. This may lead to use of higher doses or to more frequent usage which, in turn, can result in permanent use. If long-term use or overdose occurs, treatment should be discontinued immediately.

Continuous use may cause nasal congestion due to reactive hyperaemia of the nasal mucosa (rebound effect) and chronic swelling of the nasal mucosa (rhinitis medicamentosa) as well as mucosal atrophy or rhinitis sicca. Rebound effects and tachyphylaxis should stop once use of OXYMETAZOLINE CIPLA is discontinued.

OXYMETAZOLINE CIPLA contains benzalkonium chloride, its long-tern use may cause oedema of the nasal mucosa.

Medical supervision is indicated in patients with chronic rhinitis.

Dosages higher than recommended may only be used under medical supervision.

Patients should be advised to stop using OXYMETAZOLINE CIPLA if any of the following occur and to contact their medical practitioner:

- Hallucinations.
- Restlessness.
- Sleep disturbances.

Patients should take care to keep the mist away from the eyes.

Children may be especially prone to systemic absorption of oxymetazoline with resulting adverse effects.

4.5 Interaction with other medicines and other forms of interaction

The concomitant use of OXYMETAZOLINE CIPLA and certain mood-stimulating medicines with hypertensive effect (e.g. MAO inhibitors and tricyclic antidepressants) may lead to an increase in blood pressure or hypertensive crisis due to their cardiovascular activity.

The efficacy of beta-blocking medicines such as methyldopa, bethanidine, debrisoquine and guanethidine or other anti-hypertensive medicines may be reduced with concomitant use of OXYMETAZOLINE CIPLA.

Possible additive cardiovascular toxicity may occur when sympathomimetics are given with antiparkinsonian medicines, such as bromocriptine.

There is an increased risk of dysrhythmias when cardiac glycosides (e.g. digoxin) are given with sympathomimetics, such as OXYMETAZOLINE CIPLA.

There is an increased risk of ergotism when ergot alkaloids (ergotamine and methysergide) are given with sympathomimetics, such as OXYMETAZOLINE CIPLA.

4.6 Fertility, pregnancy and lactation

Pregnancy and breastfeeding

OXYMETAZOLINE CIPLA should only be used after the consultation with a medical practitioner during pregnancy and breastfeeding.

The recommended dosage must not be exceeded.

Fertility

No data are available on the effects of OXYMETAZOLINE CIPLA on human fertility.

OXYMETAZOLINE CIPLA 0,025 is indicated for paediatric use only.

4.7 Effects on ability to drive and use machines

Systemic effects with involvement of the cardiovascular or central nervous system cannot be excluded after prolonged administration of OXYMETAZOLINE CIPLA or intake of oxymetazoline containing cold remedies in doses higher than recommended. In these cases, the ability to drive a vehicle or operate machinery can be impaired.

OXYMETAZOLINE CIPLA may have influence on driving and operating machines considering reported side effects such as insomnia, nervousness, anxiety, restlessness, irritability, tremor, headache or light-headedness, dizziness, somnolence, sedation, hallucinations, convulsions, rebound hypotension and hypertension.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA system organ class	Frequency	Side effects
Immune system disorders	Frequency unknown	Hypersensitivity reactions (angioedema, rash, pruritus).
Psychiatric disorders	Less frequent	Nervousness, anxiety, irritability.
	Frequency unknown	Insomnia, restlessness.
Nervous system disorders	Less frequent	Tremor, headache or light-headedness, nervousness, anxiety, irritability.
	Frequency unknown	Dizziness, somnolence, sedation, hallucinations, convulsions.
Eye disorders	Less frequent	Eye irritation, dryness, discomfort or redness.
Cardiac disorders	Frequency unknown	Palpitations, tachycardia.
Vascular disorders	Frequency unknown	Rebound hypotension, hypertension (increased blood pressure).
Respiratory, thoracic and mediastinal disorders	Frequent	Aqueous nasal secretions, crusted nose.
	Less frequent	Discomfort, irritation, or dryness of the nose, mouth or throat, sneezing. Rebound congestion (increase in runny or stuffy nose).

	Frequency unknown	Local stinging or burning, transient irritation, rebound congestion after frequent or prolonged use, nasal discomfort (burning of the nasal mucosa), nasal dryness, sneezing, after the effect has worn off increased swelling of the mucosa (reactive hyperaemia), epistaxis.
General disorders and administration site conditions	Less frequent	Nausea.
	Frequency unknown	Fatigue, tachyphylaxis (associated with long-term use or overdose). Systemic effects have occurred after local administration. If unexpected side effects appear, a medical practitioner should be consulted immediately.

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 requested to report any suspected adverse 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

Overdosage may occur after nasal or accidental oral administration.

The efficacy of OXYMETAZOLINE CIPLA may be reduced (tachyphylaxis) with long-term use or overdose. This may lead to use of higher doses or to more frequent usage which, in turn, can result in permanent use. If long term use or overdose occurs, treatment should be discontinued immediately.

The clinical picture following intoxication with imidazol-derivatives may be unclear due to the occurrence of episodes of hyperactivity alternated with episodes of depression of the central nervous system and of the cardiovascular and pulmonary system.

Symptoms

Symptoms of an overdose may be:

Hypertension, tachycardia, palpitations, cardiac dysrhythmia, cardiac arrest, sweating, agitation, convulsions, mydriasis, nausea, vomiting, cyanosis, fever, spasms, circulatory collapse, pulmonary oedema, respiratory disorders, psychotic disorders, drowsiness, paleness, miosis, decrease in body temperature, bradycardia, shock-like hypotension, apnoea, loss of consciousness and coma.

In children above 6 years, in particular, overdose often causes dominating central nervous effects with convulsions and coma, bradycardia, apnoea as well as hypertension possibly followed by hypotension.

Therapeutic measures after overdosage

In-house intensive-care therapy is indicated in cases of severe overdose.

Administration of medicinal charcoal (absorbent) or sodium sulfate (laxative) should be performed rapidly.

A non-selective alpha-blocker can be given as antidote. If required, initiate fever lowering measures, anticonvulsive therapy and oxygen ventilation.

Vasopressors are contraindicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 16.1 – Nasal decongestants.

Pharmacotherapeutic group: Sympathomimetics, plain.

ATC code: R01AA05

Oxymetazoline is a direct-acting sympathomimetic amine. It is a topical vasoconstrictor. It acts on alpha-adrenergic receptors in the arterioles of the nasal mucosa to produce constriction, resulting in decreased blood flow and decreased nasal congestion.

Application of oxymetazoline into the nostrils leads to decongestion of the inflamed nasal mucosa and thus to a normalisation of nasal breathing.

5.2 Pharmacokinetic properties

Absorption

The effect of oxymetazoline sets in within a few minutes.

The effect of oxymetazoline persists for up to 12 hours.

Relevant absorption of pharmacodynamically effective doses of oxymetazoline following the recommended topical use is regarded as uncommon but cannot be excluded.

The absorption rate is estimated at 3,5 hours. The maximum plasma concentration can be found after 8 to 10 hours.

Elimination

Terminal serum half-life is 35 hours, and the excretion measured in faeces (1,1 % of the applied dose, after 48 hours) and urine (2,1 % of the applied dose, after 96 hours).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride 0,01 % *m/v*

Disodium hydrogen phosphate dihydrate

Liquid sorbitol 70 %

Sodium dihydrogen phosphate dihydrate (for pH adjustment)

Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep tightly closed.

Protect from light.

6.5 Nature and contents of container

OXYMETAZOLINE CIPLA 0,025: 10 mL tubular, USP Type 1, amber glass vial with a 20 mm neck finish with a polypropylene and polyethylene grade material crimp on nasal spray pump with a dip tube, and a white opaque polypropylene and polyethylene nasal adapter with an orifice tip, packed in an outer carton.

OXYMETAZOLINE CIPLA 0,05: 10 mL tubular, USP Type 1, amber glass vial with a 20 mm neck finish with a polypropylene and polyethylene grade material crimp on nasal spray pump with a dip tube, and a white opaque polypropylene and polyethylene nasal adapter with an orifice tip, packed in an outer carton.

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)

OXYMETAZOLINE CIPLA 0,025: 47/16.1/0790

OXYMETAZOLINE CIPLA 0,05: 47/16.1/0791

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation: 29 March 2019

Latest renewal: To be allocated.

10. DATE OF REVISION OF THE TEXT

27 March 2025

S.R.