PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

UNIVERSAL NASAL DROPS (Solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains:

Phenylephrine hydrochloride	2,5 mg
Naphazoline nitrate	0,25 mg
Preservatives:	
Chlorbutol	0,5 % *m/v*
Nipasept	0,15 % *m/v*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution

Clear colourless solution.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Temporary relief of nasal congestion due to the common cold, hay fever, allergic rhinitis, other upper respiratory allergies, or associated with sinusitis.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Posology

Adults and children 6 – 12 years (with adult supervision): 2 - 3 drops in each nostril, not more often than every 4 hours.

Method of administration

For nasal use.

4.3 CONTRAINDICATIONS

- Hypersensitivity to phenylephrine hydrochloride, naphazoline nitrate or to any of the ingredients listed in section 6.1.
- In patients receiving monoamine oxidase inhibitor treatment, or within 14 days of its termination.
- Safety in pregnancy and lactation has not been established (see section 4.6).
- Should not be used in the presence of high blood pressure, thyrotoxicosis or patients with cardio-vascular disease.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- This product should not be used for more than 5 days. If symptoms persist, consult a doctor.
- Prolonged use or excessive application to the nasal mucosa may produce rebound congestion and rhinorrhoea.
- The use of this container by more than one person may spread infection.
- Children may be especially sensitive to the effects of these medicines. It should be used with special precaution in children.
- Should be used with caution in patients with:
    - hypertension
    - hyperthyroidism
    - cardiovascular disease such as ischaemic heart disease, dysrhythmias, tachycardia, occlusive vascular disease, arteriosclerosis, aneurysms
    - diabetes mellitus
    - closed-angle glaucoma
    - prostatic hypertrophy
    - patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics (see section 4.5).
- UNIVERSAL NASAL DROPS contains Nipasept as a preservative, which may cause allergic reactions.

4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

- Reversal of the action of anti-hypertensive medicines may occur and therefore special care is advisable in patients receiving antihypertensive therapy. Interaction with alpha- and beta-blockers may be complex and can produce a hypertensive crisis.
- Interactions are possible with guanethidine, reserpine, maprotiline, tricyclic antidepressants, digoxin and alpha-methyldopa.
- An increased risk of dysrhythmias may occur in patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.
- Should be used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillations (see section 4.4).

4.6 FERTILITY, PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

UNIVERSAL NASAL DROPS have a negligible effect on the ability to drive or use machines. This medicine may cause dizziness which may impact the patient's ability to perform the above tasks.

4.8 UNDESIRABLE EFFECTS

MedDRA system organ class	**Frequency**	**Adverse reactions**
Metabolism and nutrition disorders:	Frequency unknown	Appetite reduction and disturbances of glucose metabolism.
Psychiatric disorders	Frequency unknown	Psychotic states.
Nervous system disorders	Frequency unknown	Anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness, sweating and headache, dizziness

Cardiac disorders	Frequency unknown	Tachycardia or bradycardia, cardiac dysrhythmias, palpitations, cardiac arrest and angina.
Vascular disorders	Frequency unknown	Vasoconstriction with resultant hypertension, the rise in blood pressure may produce cerebral haemorrhage, pulmonary oedema, hypotension with dizziness, fainting and flushing.
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Dyspnoea, excessive or prolonged use may lead to rebound congestion or rhinorrhoea.
Gastrointestinal disorders	Frequency unknown	Nausea, vomiting and hyper salivation.
Renal and urinary disorders	Frequency unknown	Difficulty in micturition and urinary retention
General disorders and administrative site conditions	Frequency unknown	May cause local irritation at the site of application, for example dryness and stinging of the mouth and throat and increased nasal discharge with sneezing.

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) or via the eReporting platform (who-umc.org) found on the SAHPRA website

You can also report side effects to Acino Pharma (Pty) Ltd., via email on drugsafety_za@acino.swiss

4.9 OVERDOSE

Accidental administration by mouth may cause symptoms of bradycardia, sweating, drowsiness and coma, particularly in children. Hypertension may be followed by rebound hypotension. (see sections 4.4 and 4.8)

Treatment is supportive and symptomatic.

Severe increase in blood pressure may occur. Treatment with alpha-adrenergic blocking agent to reduce blood pressure should be instituted if myocardial ischaemia or encephalopathy is provoked.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Category and class: A 16.1 Ear, Nose and Throat Preparations – Nasal Decongestant

Pharmacotherapeutic group: Sympathomimetics, combinations excl. corticosteroids,

ATC code: R01AB01

Alpha receptor stimulants that reduce nasal congestion by causing vasoconstriction in the nasal mucosa. When topically applied, they are effective locally and not absorbed unless swallowed.

5.2 PHARMACOKINETIC PROPERTIES

Phenylephrine hydrochloride:

Following topical application phenylephrine is absorbed through the mucosa and topical use can therefore give rise to systemic effects. Phenylephrine is extensively metabolised in the gut wall and the liver. The principal routes of metabolism are sulphonation and glucuronidation, sulphate conjugates are formed from the metabolites. Excretion is via the kidneys.

6. PHARMACEUTICAL PARTICLUARS

6.1 LIST OF EXCIPIENTS

Chlorbutol

Nipasept

Sodium chloride

Sodium metabisulphite

Purified water

6.2 INCOMPATIBILITIES

Not applicable.

6.3 SHELF LIFE

36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 ˚C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

15 ml amber glass bottles, closed with a black plastic screw cap dropper, incorporating a glass dropper pipette and rubber teat.

Pack size: 1 bottle

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Acino Pharma (Pty) Ltd

106 16th Road

Midrand

1686

8. REGISTRATION NUMBER

H1542 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7 February 1975

10. DATE OF REVISION OF THE TEXT

02 April 2025

Namibia:
Reg. no.: 14/16.1/0208
Scheduling: NS1