PROFESSIONAL INFORMATION FOR ZYLOVIN

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

ZYLOVIN 1 mg/mL nasal spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains xylometazoline hydrochloride equivalent to 1 mg xylometazoline.

Contains preservative (benzalkonium chloride 0,1 mg/mL).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear, colourless to almost colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Decongestion of nasopharyngeal mucosa in colds, sinusitis, otitis media and to facilitate rhinoscopy.

4.2 Posology and method of administration

Posology:

Adults and children over 12 years of age:

One spray into each nostril per application; a total of 3 applications a day is usually sufficient.

Do not exceed the recommended dose, especially in children and in the elderly.

Method of administration:

ZYLOVIN is for nasal administration only.

ZYLOVIN should be used after blowing the nose.

Instructions for use:

Shake gently before each use.

Before the first application, prime the pump by actuating 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be re-primed with 4 actuations.

Insert the nozzle into the nostril and press once firmly on the spray head and breathe in at the same time. Then withdraw the nozzle before releasing pressure. Repeat the operation in the other nostril. Clean and replace the protective cap.

4.3 Contraindications

- ZYLOVIN is contraindicated in cases of hypersensitivity to xylometazoline or to any of the ingredients of ZYLOVIN (see section 6.1).
- ZYLOVIN is contraindicated in the following conditions:
  - Hyperthyroidism,
  - Narrow angle glaucoma,
  - Ischaemic heart disease,
  - Rhinitis sicca or atrophic rhinitis,
  - Patients being treated with monoamine oxidase (MAO) inhibitors or 10 days after stopping treatment.

ZYLOVIN should not be employed in status post transsphenoidal hypophysectomy (or after trans-nasal or trans-oral surgical interventions in which the dura mater has been exposed).

ZYLOVIN is contraindicated in children aged less than 12 years.

4.4 Special warnings and precautions for use

ZYLOVIN should be used with caution in patients showing a strong reaction to sympathomimetic medicines, as manifested by signs of insomnia, dizziness, tremor, cardiac dysrhythmias or elevated blood pressure.

ZYLOVIN should be used with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, epistaxis, phaeochromocytoma, prostatic hypertrophy, monoamine oxidase inhibitors (MAOI) treatment or who have received them in the last two weeks (see section 4.5).

Patients with long QT syndrome treated with xylometazoline may be at risk of serious ventricular dysrhythmias.

Do not exceed the recommended dose, especially in children and in the elderly.

ZYLOVIN should not be used for more than 10 consecutive days; prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Excipient warnings:

ZYLOVIN contains 0,1 mg benzalkonium chloride in each mL. Long-term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicines and other forms of interaction

The concomitant use of xylometazoline as in ZYLOVIN with monoamine oxidase (MAO) inhibitors, tricyclic or tetracyclic antidepressants may cause an increase in blood pressure due to cardiovascular effects of these medicines (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy:

The use of xylometazoline as in ZYLOVIN during pregnancy is not advisable due to its potential systemic absorption resulting in vasoconstrictor effect.

Breastfeeding:

It is not known if xylometazoline is excreted in breast milk. ZYLOVIN should be used with caution during breastfeeding and only under medical advice.

Fertility:

No foetal toxicity or fertility studies have been carried out in animals.

4.7 Effects on ability to drive and use machines

ZYLOVIN may cause dizziness and visual disturbances (see section 4.8). Patients experiencing dizziness or visual disturbances should refrain from driving or operating machinery.

4.8 Undesirable effects

Tabulated list of adverse reactions:

System Organ Class	**Frequency**	**Side effects**
Immune system disorders	Less frequent	Hypersensitivity reaction (angioedema, skin rash, pruritis)
Nervous system disorders	Frequent Frequency unknown	Headache Insomnia, dizziness
Eye disorders	Less frequent	Transient visual disturbances
Cardiac disorders	Less frequent	Heart rate irregular, heart rate increase (palpitations)
Respiratory, thoracic and	Frequency unknown	Anosmia, epistaxis, rebound congestion after prolonged

mediastinal disorders		or excessive use, dryness of the nasal mucosa, a burning sensation in the nose and throat
Gastrointestinal disorders	Frequent	Nausea
Skin and subcutaneous tissue disorders	Less frequent	Skin rash
General disorders and administration site conditions	Frequent	Application site burning, local irritation

Reporting of suspected adverse reactions:

Reporting of 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.

4.9 Overdose

Signs

Excessive administration of ZYLOVIN or accidental ingestion may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma, convulsions and sometimes consciousness clouding. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults.

In instances of accidental poisoning in children, the clinical picture may be marked chiefly by signs such as acceleration and irregularity of the pulse, elevated blood pressure and sometimes clouding of consciousness, sweating, drowsiness, coma, convulsions, circulatory collapse.

Treatment

Symptomatic treatment under medical supervision is indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

A 16.1 Nasal Decongestants

ZYLOVIN contains xylometazoline, which belongs to the group of the arylalkyl imidazolines.

ZYLOVIN has a vasoconstrictor action, producing decongestion of the nasal and pharyngeal mucosa when administered locally.

5.2 Pharmacokinetic Properties

The effect of ZYLOVIN sets in within a few minutes and persists for several hours. Systemic absorption may occur following nasal application of xylometazoline hydrochloride solutions. It is not used systemically.

5.3 Preclinical safety data

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Disodium edetate dihydrate

Disodium hydrogen phosphate dodecahydrate

Sodium chloride

Sodium dihydrogen phosphate dihydrate

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened:

36 months.

Opened:

ZYLOVIN should not be used longer than 1 month after first opening the bottle.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

A 10 mL amber, transparent glass bottle with a white spray pump and protective cap.

The bottle is packed in an outer carton.

Each 10 mL bottle contains approximately 55 sprays.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Lamar International (Pty) Ltd

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

South Africa

8. REGISTRATION NUMBER

51/16.1/0735

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 19 July 2022