PACKAGE INSERT: Nazovin™ Adult Metered-Dose Spray and Nazovin™ Adult Nasal Drops

SCHEDULING STATUS **S1**

PROPRIETARY NAMES AND DOSAGE FORMS

Nazovin™ Adult Metered-Dose Spray

Nazovin™ Adult Nasal Drops

COMPOSITION

Each ml contains 1 mg of xylometazoline hydrochloride.

Preservative: 0,02 % *m/v* benzalkonium chloride.

Other ingredients are: Citric acid monohydrate, sodium citrate, glycerol and purified water.

Each metered spray contains 90 µg xylometazoline hydrochloride.

PHARMACOLOGICAL CLASSIFICATION

A.16.1 Nasal Decongestants.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

NAZOVIN contains xylometazoline, which belongs to the group of the arylalkyl imidazolines. It is a direct-acting sympathomimetic with marked alpha-adrenergic effects. Xylometazoline is a vasoconstrictor which reduces swelling and congestion of the nasal mucosa when administered locally.

Pharmacokinetic properties:

The effect of xylometazoline begins within 5 to 10 minutes of application and lasts for up to 10 hours.

INDICATIONS

Decongestion of naso-pharyngeal mucosa in colds, sinusitis, otitis media and to facilitate rhinoscopy.

CONTRAINDICATIONS

- Hypersensitivity to xylometazoline or any of the other ingredients of NAZOVIN Adult Metered-Dose Spray and Nasal Drops.
- Ischaemic heart disease
- Hyperthyroidism
- Patients being treated with monoamine oxidase inhibitors (MAO Inhibitors) or within 14 days after discontinuing treatment.

- NAZOVIN should not be administered in status post sphenoidal hypophysectomy (or after transnasal or transoral surgical interventions in which the dura mater has been exposed).

WARNINGS AND SPECIAL PRECAUTIONS

- NAZOVIN Adult Metered-Dose Spray and Nasal Drops should be used with caution in children and generally avoided in children under 12 years of age.
- Concurrent use of tricyclic or tetracyclic antidepressants may potentiate the systemic effects of xylometazoline.
- Do not exceed the recommended dose, especially in children and in the elderly.
- Caution should be exercised when administering NAZOVIN to patients with hypertension, pheochromocytoma, cardiovascular disease (such as dysrhythmias, tachycardia, occlusive vascular disease and aneurysm), narrow-angle glaucoma, diabetes mellitus and prostatic hypertrophy.
- NAZOVIN should be used with caution in patients showing a strong reaction to sympathomimetic agents, as evidenced by signs of insomnia, dizziness, etc.
- NAZOVIN should not be administered continuously for periods exceeding 7 days as prolonged or excessive use may cause rebound congestion. Chronic use may also lead to atrophic rhinitis.
- NAZOVIN is possibly porphyrinogenic.

(see **INTERACTIONS**)

INTERACTIONS

Topical application of NAZOVIN may result in interactions as xylometazoline is absorbed through the nasal mucosa.

Concomitant use of NAZOVIN with tricyclic or tetracyclic antidepressants may potentiate the systemic effects of xylometazoline.

Sympathomimetic nasal decongestants may cause a hypertensive crisis if used concurrently with MAO Inhibitors.

Reversal of the action of anti-hypertensive agents may occur.

(see **WARNINGS AND SPECIAL PRECAUTIONS** and **CONTRAINDICATIONS**)

PREGNANCY AND LACTATION

NAZOVIN should not be used during pregnancy due to its potential systemic absorption and should be used with caution during lactation.

DOSAGE AND DIRECTIONS FOR USE

NAZOVIN Adult Metered-Dose Spray and Nasal Drops are for nasal administration only and should be used after blowing the nose.

NAZOVIN Adult Metered-Dose Spray and Nasal Drops should not be used in children under the age of 12 years.

Adults and children over 12 years of age:

NAZOVIN Adult Metered-Dose Spray:	One spray from the metered-dose spray into each nostril per application.
NAZOVIN Adult Nasal Drops:	2 to 3 drops of the 1 mg/ml solution into each nostril per application.

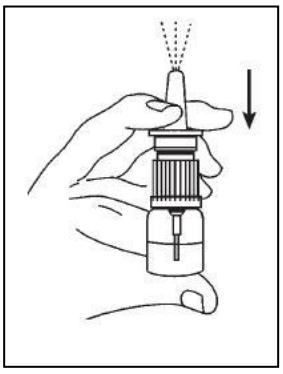
A total of 3 applications a day is usually sufficient.

Use of NAZOVIN Adult Metered-Dose Spray:

Before using NAZOVIN Adult Metered-Dose Spray gently blow your nose. Wash your hands before removing the protective cap. Before the first application, perform several pumping motions until an even spray appears in the air.

Insert the nozzle into the nostril and press once firmly on the spray head and inhale at the same time. Then withdraw the nozzle before releasing pressure. Repeat the process in the other nostril.

Wipe the spray nozzle clean after each use and replace the protective cap.



Do not swallow the medication if it drips into the throat.

To prevent contamination do not touch the spray nozzle tip or allow it to touch any other surface.

Use of NAZOVIN Adult Nasal Drops:

Before using NAZOVIN Adult Nasal Drops gently blow your nose.

Wash your hands before removing the protective cap.

Tilt your head back while sitting on a chair or lying down.

Hold the dropper over the affected nostril and instil 2 to 3 drops into the nostril.

Keep your head tilted for a few minutes. Repeat the process in the other nostril if needed.
Wipe the dropper nozzle clean after each use and replace the protective cap.

Do not swallow the medication if it drips into the throat.
Do not touch the dropper tip or allow it to touch your nose or any other surface to prevent contamination.

SIDE EFFECTS

NAZOVIN may cause side effects.

General disorders and administrative site conditions:

Frequent:

Local irritation, burning sensation in nose and throat, dryness of nasal mucosa, sneezing

Frequency unknown:

Epistaxis, rebound congestion, anosmia

Nervous system disorders:

Frequency unknown:

Headache, insomnia, dizziness

Gastrointestinal disorders:

Frequency unknown:

Nausea

Cardiac disorders:

Frequency unknown:

Palpitations

Skin and subcutaneous tissue disorders:

Less frequent:

Skin rash

Immune system disorders:

Less frequent:

Systemic allergic reactions

Eye disorders:

Less frequent:

Transient visual disturbances

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Signs and symptoms:

Overdosage or accidental dosage by mouth may, particularly in children, cause the following: acceleration and irregularity of pulse, elevated blood pressure, reduced body temperature and sometimes clouding of consciousness, sweating, drowsiness, coma, convulsions and circulatory collapse.

Treatment:

Symptomatic treatment under medical supervision is indicated.

IDENTIFICATION

Clear, colourless liquid.

PRESENTATION

Nazovin Adult Metered-Dose Spray:

10 ml brown glass bottle with a clear cap and a white spray pump enclosed in a cardboard carton. Each container delivers approximately 110 metered sprays, when used as recommended.

Nazovin Adult Nasal Drops:

10 ml brown glass bottle with a white polypropylene cap and a clear glass pipette dropper with a yellow rubber bulb enclosed in a cardboard carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a well-closed container. Keep container in outer carton when not in use.
Do not use more than 6 months after opening.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

Nazovin Adult Metered-Dose Spray: 46/16.1/0311
Nazovin Adult Nasal Drops: 46/16.1/0853

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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™ NAZOVIN is a trademark of Actor Pharma (Pty) Ltd.

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