PATIENT INFORMATION LEAFLET FOR NAZOVIN™ ADULT METERED-DOSE SPRAY AND NAZOVIN™ ADULT NASAL DROPS

SCHEDULING STATUS **S1**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NAZOVIN™ 1,0 mg/ml Adult Metered-Dose Spray

NAZOVIN™ 1,0 mg/ml Adult Nasal Drops

Xylometazoline hydrochloride

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

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

- Keep this leaflet. You may need to read it again.
- Do not share NAZOVIN with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT NAZOVIN CONTAINS

The active substance is xylometazoline hydrochloride.

Each ml contains 1 mg xylometazoline hydrochloride.

The other ingredients are: Benzalkonium chloride 0,02 % *m/v* (as preservative), citric acid monohydrate, glycerol, sodium citrate and purified water.

Each metered spray contains 90 µg xylometazoline hydrochloride.

WHAT NAZOVIN IS USED FOR

NAZOVIN temporarily relieves nasal congestion in colds, sinusitis and otitis media. NAZOVIN causes the blood vessels in the nose to become narrower resulting in a decrease of swelling and congestion. The effect of xylometazoline begins within 5 to 10 minutes and lasts for up to 10 hours.

BEFORE YOU USE NAZOVIN

Do not use NAZOVIN:

- if you are hypersensitive (allergic) to xylometazoline or any of the ingredients of NAZOVIN Adult Metered-Dose Spray and Nasal Drops.

- if you suffer with ischaemic heart disease which is a condition that affects the supply of blood to the heart due to narrowed or blocked blood vessels.
- if you have hyperthyroidism (when the thyroid gland is overactive; nervousness, anxiety, rapid heartbeat, hand tremor and sleep problems among other symptoms may be experienced).
- if you are being treated with monoamine oxidase inhibitors (MAO Inhibitors) which are used in the treatment of depression or within 14 days after stopping treatment.
- after having a sphenoidal hypophysectomy (i.e. after you have had recent brain surgery).

Take special care with NAZOVIN:

- NAZOVIN should not be over used or used continuously for more than 7 days as it may cause your nose to become more stuffy and may lead to chronic inflammation of the nose.
- Consult a doctor if your symptoms persist.
- if you suffer from or have any of the following conditions: hypertension, cardiovascular disease, narrow-angle glaucoma and diabetes mellitus.
- if you have had a strong reaction to sympathomimetic medicines such as pseudoephedrine manifested as an inability to sleep, dizziness, etc.
- Do not use more than the recommended doses in elderly patients and children.
- NAZOVIN may cause or worsen porphyria.

Pregnancy and Breastfeeding:

NAZOVIN should not be used during pregnancy.

NAZOVIN should be used with caution during lactation.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

Driving and using machinery:

You should not drive or operate machinery until you know how NAZOVIN affects you.

Using other medicines with NAZOVIN:

Before using NAZOVIN tell your doctor or pharmacist:

- if you are taking any other sympathomimetic medicines (e.g. pseudoephedrine).
- if you are taking tricyclic or tetracyclic anti-depressants (e.g. amitriptyline).

You should not take NAZOVIN together with tricyclic or tetracyclic anti-depressants (e.g. amitriptyline) as these may increase the effects of xylometazoline.

NAZOVIN may cause a significant increase in blood pressure if used together with MAO Inhibitors.

HOW TO USE NAZOVIN

Always use NAZOVIN as your doctor or pharmacist has told you or according to the leaflet. You should check with your doctor or pharmacist if you are unsure.

NAZOVIN Adult Metered-Dose Spray and Nasal Drops are for nasal administration only.

NAZOVIN Adult Metered-Dose Spray and Nasal Drops 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, unless otherwise prescribed by your doctor.

In children 2 to 12 years of age, NAZOVIN Paediatric Nasal Drops of 0,5 mg/ml may be used.

Adults and children over 12 years of age:

The usual dose is:

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.

How to use 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.

Use your finger to close the nostril on the side not receiving the medication.

Keep your head upright and insert the nozzle into the open nostril.

Press once firmly on the spray head and breathe in at the same time.

Sniff hard a few times to ensure that the medication reaches deep into the nose.

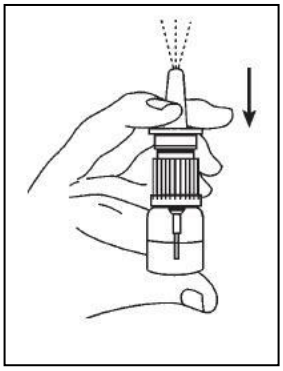
Remove the nozzle before releasing pressure on the spray head.

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.





How to use 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.

If you use more NAZOVIN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

Depending on the severity of the overdosage, the doctor will start the appropriate treatment.

POSSIBLE SIDE EFFECTS

NAZOVIN can have side effects. Not all side effects reported for NAZOVIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using NAZOVIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

These are very serious side effects.
If you have them, you may have had a serious allergic reaction to NAZOVIN. 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 changes in the way your heart beats, for example, if you notice it beating faster.
This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects:

- Most frequent: local nasal irritation, burning sensation in nose and throat, dryness of nasal mucosa, sneezing.
- Less frequent: transient visual disturbances.
- Frequency unknown: nose bleeds, rebound congestion, loss of sense of smell, headache, an inability to sleep, dizziness, nausea.

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

STORING AND DISPOSING OF NAZOVIN

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. Store all medicines out of reach of children.
Do not use this medicine after the expiry date stated on the bottle and carton.
Return all unused medicines to your pharmacist.
Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION OF NAZOVIN

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.

IDENTIFICATION OF NAZOVIN

Clear, colourless liquid.

REGISTRATION NUMBER

Nazovin Adult Metered-Dose Spray: 46/16.1/0311

Nazovin Adult Nasal Drops: 46/16.1/0853

NAME AND ADDRESS OF REGISTRATION HOLDER

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

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Nazovin Adult Metered-Dose Spray: NS1 16/16.1/0150

Nazovin Adult Nasal Drops: NS1 16/16.1/0149

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