**PATIENT INFORMATION LEAFLET FOR NAZOVIN™ PAEDIATRIC NASAL DROPS**

**SCHEDULING STATUS** **S1**

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**Nazovin™ 0,5 mg/ml Paediatric Nasal Drops**

Xylometazoline hydrochloride

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

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

- Keep this leaflet. You may need to read it again.
- Do not share NAZOVIN Paediatric Nasal Drops between more than one child.
- 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 PAEDIATRIC NASAL DROPS CONTAINS**

The active substance is xylometazoline hydrochloride.

Each ml contains 0,5 mg xylometazoline hydrochloride.

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

**WHAT NAZOVIN PAEDIATRIC NASAL DROPS IS USED FOR**

NAZOVIN Paediatric Nasal Drops temporarily relieves nasal congestion in colds, sinusitis and otitis media. NAZOVIN Paediatric Nasal Drops 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 PAEDIATRIC NASAL DROPS**

**Do not use NAZOVIN Paediatric Nasal Drops:**

- if your child is hypersensitive (allergic) to xylometazoline or any of the ingredients of NAZOVIN Paediatric Nasal Drops.
- if your child suffers 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 your child has hyperthyroidism (when the thyroid gland is overactive; nervousness, anxiety, rapid heartbeat, hand tremor and sleep problems may be experienced among other symptoms).
- if your child is being treated with monoamine oxidase inhibitors (MAO Inhibitors) which are used in the treatment of depression or within 14 days after stopping treatment.
- if your child has had a recent sphenoidal hypophysectomy (i.e.brain surgery).

**Take special care with NAZOVIN Paediatric Nasal Drops:**

- NAZOVIN Paediatric Nasal Drops should not be over used or used continuously for more than 5 days as it may cause your child's nose to become more stuffy and may lead to chronic inflammation of the nose.
- Consult a doctor if your child's symptoms persist.
- If your child suffers from any of the following conditions: hypertension, cardiovascular disease, narrow-angle glaucoma and diabetes mellitus.
- If your child has 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.
- NAZOVIN may cause or worsen porphyria.

**Pregnancy and breastfeeding:**

NAZOVIN Paediatric Nasal Drops should not be used during pregnancy. NAZOVIN Paediatric Nasal Drops 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:**

Driving and using machinery should be avoided until the effects of NAZOVIN Paediatric Nasal Drops are known.

**Using other medicines with NAZOVIN Paediatric Nasal Drops**:

Before using NAZOVIN Paediatric Nasal Drops tell your doctor or pharmacist:

- if your child is taking any other sympathomimetic medicines (e.g. pseudoephedrine).
- if your child is taking tricyclic or tetracyclic anti-depressants (e.g. amitriptyline).

NAZOVIN Paediatric Nasal Drops should not be taken together with tricyclic or tetracyclic anti-depressants (e.g. amitriptyline) as these may increase the effects of xylometazoline.
NAZOVIN Paediatric Nasal Drops may cause a significant increase in blood pressure if used together with MAO Inhibitors.

**HOW TO USE NAZOVIN PAEDIATRIC NASAL DROPS**

Always use NAZOVIN Paediatric Nasal Drops as your doctor or pharmacist has told you or according to this leaflet. You should check with your doctor or pharmacist if you are unsure.
NAZOVIN Paediatric Nasal Drops is for nasal administration only.
NAZOVIN Paediatric Nasal Drops should be used after blowing the nose.

**Children 2 to 12 years of age:**

1 to 2 drops of the 0,5 mg/ml solution into each nostril once or twice daily, is usually sufficient.
A total of 2 applications a day should not be exceeded.
Do not use this bottle of nasal drops for more than 6 months after opening the bottle.
To prevent cross infection, each bottle should be used by one child only.

**How to use NAZOVIN Paediatric Nasal Drops:**

NAZOVIN Paediatric Nasal Drops should be used after blowing the nose.
Wash your hands before removing the protective cap.
Tilt your child's head back whilst they are sitting on a chair or lying down.
Hold the dropper over the affected nostril and instil 1 to 2 drops.
Keep your child's 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.

The medication should not be swallowed if it drips into the throat.
Do not touch the dropper tip or allow it to touch the nose or any other surface to prevent contamination.

**If you use more NAZOVIN Paediatric Nasal Drops 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 Paediatric Nasal Drops can have side effects. Not all side effects reported for NAZOVIN Paediatric Nasal Drops are included in this leaflet. Should your child's general health worsen or if your child experiences 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 Paediatric Nasal Drops 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 your child has them, your child may have had a serious allergic reaction to NAZOVIN Paediatric Nasal Drops. You child 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 child's heart beats, for example, if you notice it beating faster.
This is a serious side effect. Your child 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 PAEDIATRIC NASAL DROPS**

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 PAEDIATRIC 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 PAEDIATRIC NASAL DROPS**

Clear, colourless liquid.

**REGISTRATION NUMBER:**

46/16.1/0854

**NAME AND ADDRESS OF REGISTRATION HOLDER**

Actor Pharma (Pty) Ltd[1]
Unit 7, Royal Palm Business Estate
646 Washington Street, Halfway House
Midrand, 1685
Gauteng, South Africa

**DATE OF PUBLICATION**

09 January 2017

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

**1** Company Registration number: 2008/008787/07.

**Namibia: NS1 16/16.1/0151**

NAZP/PIL/01/01.2017