SCHEDULING STATUS S1

PROPRIETARY NAME AND DOSAGE FORM

Nazovin™ Paediatric Nasal Drops

COMPOSITION

Each ml contains 0,5 mg of xylometazoline hydrochloride.

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

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

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 Paediatric 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 Paediatric Nasal Drops should be used with caution in children and generally avoided in children under 2 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 Paediatric Nasal Drops should not be administered continuously for periods exceeding 5 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 Paediatric Nasal Drops are for nasal administration only and 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.

Use of Nazovin Paediatric Nasal Drops:

Before using NAZOVIN Paediatric Nasal Drops ensure that the nose is gently blown.

Wash your hands before removing the protective cap.

Tilt the head back whilst sitting on a chair or lying down.

Hold the dropper over the affected nostril and instil 1 to 2 drops into the nostril.

Keep the 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.

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

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

46/16.1/0854

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