SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) of Drutivin® Nasal Drops(Xylometazoline Hydrochloride 0.05%w/v – Pediatric, 0.1%w/v - Adult)

1. NAME OF THE MEDICINAL PRODUCT
Drutivin® Nasal Drops(Xylometazoline Hydrochloride 0.05%w/v – Pediatric, 0.1%w/v - Adult)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Drutivin® Pediatric Nasal Drops contains:
Xylometazoline Hydrochloride ……..0.5mg

Each ml of Drutivin® Adult Nasal Drops contains:
Xylometazoline Hydrochloride ……..1mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form Solution/Drops

4. Clinical particulars

4.1 Therapeutic indications

Acute colds, vasomotor rhinitis, hay fever, to aid drainage of secretions in infections of the paranasal sinuses, to facilitate rhinoscopy.

4.2 Posology and method of administration

Posology *Adult*

Adults and Children over 7 years(all indications): 2 or 3 drops of 0.1% in each nostril up to 4 times daily.

Pediatric

Children between 2 and 6 years under adult supervision (all indications): 1 or 2 drops of 0.05%, in each nostril up to 3 times a day.

Infants up to 2 years: 1 drop of 0.05% solution into each nostril 3 times daily.

4.3 Contraindications

Known hypersensitivity to Drutivin

Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater

Narrow-angle glaucoma

Rhinitis sicca or atrophic rhinitis.

Drutivin 0.1% is contraindicated in children aged less than 12 years

People with phaeochromocytoma or prostatic hypertrophy or receiving monoamine oxidase inhibitors (MAOI) treatment or who have received them in the last two weeks.

4.4 Special warnings and precautions for use

Patients are advised not to take decongestants for more than seven consecutive days. Prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Drutivin, like other preparations belonging to the same class of active substances, should be used only with caution in patients showing a strong reaction to sympathomimetic agents as evidenced by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.

Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism or diabetes mellitus.

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

Patients are advised not to take decongestants for more than five consecutive days. Prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Drutivin, like other preparations belonging to the same class of active substances, should be used only with caution in patients showing a strong reaction to sympathomimetic agents as evidenced by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.

Use with caution in occlusive vascular disease

If any of the following occur, Drutivin should be stopped

• Hallucinations

• Restlessness

• Sleep disturbances

Keep away from eyes.

Keep medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant use of xylometazoline with **monoamine oxidase (MAO) inhibitors**, **reversible inhibitors of monoamine oxidase (RIMAs)** or **tri- and tetra-cyclic antidepressants**, may cause an increase in blood pressure due to the cardiovascular effects of these substances (*see Contraindications*).

Moclobemide: risk of hypertensive crisis.

Antihypertensives (including adrenergic neurone blockers & beta-blockers): Drutivin may block the hypotensive effects.

Cardiac glycosides: increased risk of dysrhythmias

Ergot alkaloids (ergotamine & methylsergide): increased risk of ergotism

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension

Oxytocin – risk of hypertension

4.6 Fertility, pregnancy and lactation

No foetal toxicity or fertility studies have been carried out in animals. In view of its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using Drutivin during pregnancy. No evidence of any adverse effect on the breast-fed infant. However, it is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and Drutivin should be used only on the advice of a doctor whilst breastfeeding.

4.7 Effects on ability to drive and use machines None known.

4.8 Undesirable effects

The adverse effects listed below are classified by system organ class and frequency according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000).

MeDRA SOC	Adverse reaction	Frequency
Immune System Disorders	Hypersensitivity reaction (angioedema, rash, pruritus)	Very rare

Nervous System Disorders	Headache	Common
Eye Disorders	Transient visual impairment	Very rare
Cardiac Disorders	Heart rate irregular Heart rate increased	Very rare Very rare
Respiratory, thoracic and mediastinal disorders	Nasal Dryness Nasal Discomfort Epistaxis	Common Common Uncommon
Gastrointestinal disorders	Nausea	Common
General disorders and administration site	Application site burning	Common

Other side effects include:

• A burning sensation in the nose and throat

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4.9 Overdose

Symptoms and signs

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

Treatment

Appropriate supportive measures should be initiated in all individuals suspected of an overdose, and urgent symptomatic treatment under medical supervision is indicated when warranted. This would include observation of the individual for several hours.

5.1 Pharmacodynamic properties Pharmacodynamic effects

Drutivin Adult Nasal Drops is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the

nose and neighbouring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Drutivin Adult Nasal Drops begins within a few minutes and lasts for up to 10 hours. Drutivin Adult Nasal Drops is generally well tolerated and does not impair the function of ciliated epithelium.

Drutivin Child Nasal Drops is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Drutivin Child Nasal Drops begins within a few minutes and lasts for up to 10 hours. Drutivin Child Nasal Drops is generally well tolerated and does not impair the function of ciliated epithelium.

5.2 Pharmacokinetic properties

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

Xylometazoline HCL
Sodium Chloride
Sodium Citrate
Disodium Edetate
Hydrochloric Acid
Benzalkonium Chloride
Water for Injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30 °C. Protect from light and moisture. Replace cap immediately after use. Discard after 28 days of opening the bottle.

6.5 Nature and contents of container
Lupolen bottles containing 10ml of the 0.1% adult Nasal drops and 5ml of 0.05% Pediatric Nasal drops.

6.6 Special precautions for disposal and other handling

Keep out of the reach of children. **7.0**

Applicant/Manufacturer

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