# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. Name of the medicinal product

Xylometazoline hydrochloride 0.05% w/v nasal spray solution
Sinutab children's nasal spray

Xylometazoline hydrochloride 0.1% w/v nasal spray solution
Sinutab adult nasal spray

## 2. Qualitative and quantitative composition

Sinutab children's nasal spray
Each mL of solution contains 0.5 mg of carmellose sodium.

Sinutab adult nasal spray
Each mL of solution contains 1 mg of carmellose sodium.

Excipient with known effect
Each mL of solution also contains 0.4 mg of benzalkonium chloride. See section 4-4.

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Nasal spray solution.

A clear colourless solution, odourless or with a slight characteristic odour.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Xylometazoline hydrochloride is indicated for the relief of nasal congestion accompanying hay fever, allergic rhinitis, colds and sinusitis.

### 4.2 Posology and method of administration

**Posology**

***Children above 12 years, adults and the elderly (all indications):***
2 or 3 drops in each nostril up to 3 times daily. Do not exceed 3 applications daily into each nostril. The drops are suitable for children over 12 years of age. The recommended dose should not be exceeded.

***Children between 6 and 12 years under adult supervision (all indications):***
1 or 2 drops, in each nostril up to 2 times a day. Not to be used for more than 5 days without the advice of a doctor. No more than 2 doses should be given in any 24 hours.

Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

**Method of administration**
Nasal use.

**4.3 Contraindications**
- Hypersensitivity to the active substance or any of the excipients listed in section 6.1.
- Xylometazoline hydrochloride is contraindicated in children under 6 years of age.
- Concomitant use of other sympathomimetic decongestants.
- Cardiovascular disease including hypertension.
- Diabetes mellitus Phaeochromocytoma Prostatic hypertrophy Hyperthyroidism closed-angle glaucoma.
- Monoamine oxidase inhibitors (MAOIs, or within 14 days of stopping treatment, see section 4.5).
- Beta-blockers – (see section 4.5).
- Inflammation of the skin and/or mucosa of the nasal vestibule.
- Trans-sphenoidal hypophysectomy or nasal surgery exposing the dura mater.
- Rhinitis sicca or atrophic rhinitis.

**4.4 Special warnings and precautions for use**
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.

Xylometazoline hydrochloride, 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, tremors, cardiac arrhythmias or elevated blood pressure.

Use with caution in occlusive vascular disease and patients taking tri or tetra-cyclic antidepressant treatment.

If any of the following occur, xylometazoline hydrochloride should be stopped
- Hallucinations
- Restlessness
- Sleep disturbances.

*Excipients*
This medicine contains **benzalkonium chloride**. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Long-term use may cause oedema of the nasal mucosa.

The small amount of benzalkonium chloride in this medicine is unlikely to cause irritation over short-term use.

**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): Xylometazoline 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 – the risk of hypertension.

**4.6 Pregnancy, fertility and lactation**
No foetal toxicity or fertility studies have been carried out in animals. Given its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using xylometazoline hydrochloride during pregnancy.

No evidence of any adverse effect on the breastfed infant. However, it is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and xylometazoline hydrochloride should be used only on the advice of a doctor whilst breastfeeding.

**4.7 Effects on the ability to drive and use machines**
Xylometazoline hydrochloride has no or negligible influence on the ability to drive and use machines.

**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 |
| | Irritability, Anxiety, Restlessness, Excitability, Insomnia, Hallucinations and Paranoid Delusions - particularly with prolonged and/or excessive use | Unknown |
| Eye Disorders | Transient visual impairment | Very rare |
| Cardiac Disorders | Heart rate irregular, Heart rate increased - particularly with prolonged and/or excessive use | Very rare |
| | Other cardiac dysrhythmias and hypertension- particularly with prolonged and/or excessive use | Unknown |

| | | |
|---|---|---|
| Respiratory, thoracic and mediastinal disorders | Nasal Dryness<br>Nasal Discomfort<br>Epistaxis | Common<br>Common<br>Uncommon |
| Gastrointestinal disorders | Nausea | Common |
| General disorders and administration site | Application site burning | Common |
| | Tolerance with diminished effect – especially with prolonged and/or heavy use | Unknown |
| | Rebound congestion (rhinitis medicamentosa) – especially with prolonged and/or heavy use | Unknown |
| | Irritation & dryness | Unknown |

**Reporting of suspected adverse reactions**
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Adverse Drug Reaction (ADR)/ Serious Adverse Event (SAE) electronic form linked to the MCAZ database using the following link: https://primaryreporting.who-umc.org/ZW.

**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. Pharmacological properties

**5.1 Pharmacodynamic properties**
Pharmacological classification: 20.2.4 Ear, nose, throat and mouth preparations: Other decongestants and anti-allergics

Xylometazoline hydrochloride 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 xylometazoline hydrochloride begins within a few minutes and lasts for up to 10 hours.

Xylometazoline hydrochloride is generally well tolerated and does not impair the function of ciliated epithelium.

In a double-blind, saline solution-controlled study in patients with the common cold, the decongestant effect of xylometazoline hydrochloride was significantly superior ($p<0.0001$) to a saline solution based on rhinomanometry measurement 1 hour after administration of the study drugs.

**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**
Not applicable.

## 6. Pharmaceutical particulars

**6.1 List of excipients**
Benzalkonium chloride
Sorbitol
Sodium chloride
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Disodium edetate
Purified water

**6.2 Incompatibilities**
Not applicable.

**6.3 Shelf life**
24 months.

**6.4 Special precautions for storage**
Store below 25°C.

**6.5 Nature and contents of the container**
An amber type 3 glass bottle with an integral metered snap-on 0.140ml pump assembly consisting of a white plastic actuator and natural polyethylene pull-off overcap.

Fill volume: 10 ml and 15 ml.
Pack size: 1 bottle per carton.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal and other handling**
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. APPLICANT

Johnson & Johnson (Pty) Ltd
241 Main Road, Retreat
Cape Town, 7945
South Africa

## 8. MANUFACTURER

Famar Orleans
5 Avenue de Concyr, Orleans
Cedex 2, 45071
France

## 9. REGISTRATION DETAILS

Sinutab children's nasal spray
Zimbabwe registration number: 2023/20.2.4/6525
Zimbabwe category for distribution: Pharmacy Medicines (P.)

Sinutab adult nasal spray
Zimbabwe registration number: 2023/20.2.4/6526
Zimbabwe category for distribution: Pharmacy Medicines (P.)

## 10. DATE OF REVISION OF THE TEXT

March 2024