SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Otrivin metered-dose nasal spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: xylometazoline hydrochloride.

Metered dose nasal spray 0.1% - Each dose of spray contains 0.14 mg xylometazoline hydrochloride.
Metered dose nasal spray 0.05% - Each dose of spray contains 0.035 mg xylometazoline hydrochloride.
Excipients to be considered in the drug product:
benzalkonium chloride For the full list of excipients, see section 6.1.

3. DOSAGE FORM

Metered-dose nasal spray.

Clear colorless to slightly yellowish solution, practically odorless.

4. CLINICAL PARTICULARS

4.1. Indications

Relief of nasal congestion due to colds, hay fever or other allergic rhinitis, sinusitis. To aid drainage of secretions in sinus conditions. In otitis media, as an adjuvant to decongest the nasopharyngeal mucosa. To facilitate rhinoscopy.

4.2. Posology and method of administration

Posology

Metered dose nasal spray 0.05%

Children 2–11 years old use under adult supervision.

One spray into each nostril, once or twice daily (every 8 to 10 hours). Do not exceed 3 applications daily into each nostril.
Children aged 1-2 years: use according to the doctor's prescription. Children aged below 1 year: the product should not be used.

Otrivin Metered dose nasal spray 0.1%

Adults and children over 12 years of age

One spray into each nostril up to 3 times daily as needed. Do not exceed 3 applications daily into each nostril.
It is recommended to make the last application shortly before retiring to bed.

Method of administration
Intranasal.

How to use the metered-dose spray:

Clean (blow) the nose thoroughly before use. Remove the protective cap. Activate the pump several times before the first use. The metered-dose spray is ready to use for all other applications. If the mist is not fully emitted after pumping, e.g. after a break from use, activate the pump again 4 times. Insert the spray opening into the nostril and press down strongly on the nozzle, once. Optimal distribution of the mist can be achieved by breathing in lightly through the nose while spraying. Replace the protective cap after use.

4.3. Contraindications

Hypersensitivity to xylometazoline or any of the excipients listed in section 6.1.

- condition after transsphenoidal hypophysectomy or after trans nasal or trans oral surgeries which expose the dura mater,
- narrow angle glaucoma,

- Rhinitis sicca or atrophic rhinitis,

- surgery on the cerebral membranes (in the past history),

Metered dose nasal spray 0.05% is contraindicated in children aged less than 1 year old. Metered dose nasal spray 0.1% is contraindicated in children aged less than 12 years.

4.4. Special warnings and precautions for use

Exercise caution in case of:

- hypersensitivity to adrenergic products associated with insomnia, dizziness, arrhythmia, tremor, increased blood pressure;
- hypertension

- severe cardiovascular diseases (including coronary heart disease, angina pectoris),

- hyperthyroidism

- diabetes mellitus

- prostate hyperplasia;

- pheochromocytoma,

- monoamine oxidase inhibitors (MAOI) treatment or patients who have received them in the last two weeks and patients on tri and tetra-cyclic antidepressant treatment (see Interactions).

There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) on treatment with sympathomimetic drugs, including xylometazoline. Symptoms included sudden onset of severe headache, nausea, vomiting, and visual disturbances. In most cases, the condition has improved or the event has resolved within a

few days after appropriate treatment. Otrivin should be discontinued immediately and medical advice should be sought if signs/symptoms of PRES/RCVS develop.
Continuous administration for more than 10 days is not advised.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment. The recommended doses should not be exceeded, especially in children and elderly patients.
Long-term (> 10 days) or excessive administration of the drug may cause rebound effect (drug-induced rhinitis) and/or nasal mucosa atrophy.
Patients with long QT syndrome using xylometazoline may be at increased risk of developing serious ventricular arrhythmias.

4.5. Interaction with other medicinal products and other forms of interaction Xylometazoline is contraindicated in patients treated with monoamine oxidase inhibitors, including 14 days after their withdrawal.
Co-administration of tricyclic or tetracyclic antidepressants and sympathomimetic products may enhance sympathomimetic effect of xylometazoline, therefore this combination is contraindicated.

4.6. Fertility, pregnancy and breastfeeding

Pregnancy

The product should not be used during pregnancy. Lactation
During breastfeeding, the product should only be used after thorough evaluation of risk-benefit ratio for the mother and infant under supervision of a doctor. Do not exceed the recommended dosage.

4.7. Effects on ability to drive and use machines

Otrivin has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Summary of adverse reactions

The adverse reaction frequency was determined in compliance with the classification of the World Health Organization as following: 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); very rare (< 1/10,000).
Immune system disorders:

Very rare: hypersensitivity reactions (angioedema, rash, pruritus).

Psychiatric disorders:

Rare: insomnia, depression (at long-term application at high doses).

Nervous system disorders:

Common: headache.

Eye disorders:

Very rare: Transient visual impairment.

Cardiac disorders:

Rare: palpitations.

Very rare: tachycardia, arrhythmia.

Vascular disorders:

Rare: increased blood pressure.

Respiratory, thoracic and mediastinal disorders:

Common: nasal irritation and/or dryness, burning, tingling, sneezing, nasopharyngeal hypersecretion, drug-induced rhinitis.

Gastrointestinal disorders:

Common:
nausea. Rare:
vomiting.

General disorders and reactions at the injection site:

Common: burning at the injection site.

Reporting of suspected adverse reactions

Healthcare professional are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9. Overdose

Symptoms

Excessive administration of topical xylometazoline or its accidental ingestion may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma and convulsions. Increased blood pressure may be followed by its abrupt decrease.

Treatment

Relevant supporting measures should be taken in case of suspected overdose, immediate symptomatic therapy under medical monitoring is indicated in some cases. This would include follow-up for several hours. In case of severe toxicity with cardiac arrest, resuscitation measures should be performed for at least 1 hour.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: drugs for nasal disorders treatment; decongestants and other topical agents; sympathomimetics.
ATC code: R01AA07

Mechanism of action and pharmacodynamic effects

Xylometazoline belongs to local vasoconstrictive agents (decongestants) with α-adrenomimetic effect, causes nasal vasoconstriction, eliminating oedema and hyperemia of nasopharyngeal mucosa. Xylometazoline also reduces related mucus hypersecretion and relieves drainage of congested nasal passages and thus improves nasal breathing during nasal congestion.
Xylometazoline is well tolerated, even by patients with a sensitive nasal mucosa, and its effect does not impede the mucus drainage. Xylometazoline has balanced pH value typical for the nasal cavity. The drug contains inactive ingredients - sorbitol and hypromellose (methylhydroxypropylcellulose) which act as humidifiers. Therefore, humidifying formula reduces the symptoms of nasal irritation and dryness occurring upon long-term use of xylometazoline. At therapeutic concentrations, the drug does not irritate nasal mucosa and does not cause hyperemia. The effect develops 2 minutes after dosing and continues for 12 hours (e.g. overnight). *In vitro* studies have shown that xylometazoline inhibits the infectious activity of human rhinoviruses associated with the common cold.

5.2. Pharmacokinetics

At local application at the recommended doses, the product is not almost absorbed, plasma concentration is below the limit of detection.

6. PHARMACEUTICAL PROPERTIES

6.1. List of excipients

Sodium dihydrogen phosphate
dihydrate Disodium phosphate
dodecahydrate Disodium edetate
Benzalkonium chloride
solution Sorbitol
Hypromellose
Sodium chloride
Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

storage Should be kept out of the

reach of children. Protect from heat.
Do not store above 30 °C.

6.5. Nature and content of primary packaging

10 ml bottle mounted with a snap-on metered-dose pump including an actuator and mounted with a protective cap. Vial and patient information leaflet in a carton.

6.6. Special precautions for the disposal of the medicinal product or waste after the medicinal product use and other manipulation with the medicinal product.

There are no special requirements to disposal.

7. MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Kenya) Ltd
Industrial Area, Likoni Road
P.O. Box 78392 – 00507

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Kenya

8. MARKET AUTHORIZATION NUMBER

H2025/CTD12941/26700

9. DATE OF FIRST AUTHORIZATION

NA

10. DATE OF REVISION OF TEXT

August 2024