1 NAME OF THE MEDICINAL PRODUCT

Otrivine Sinusitis Relief, 0.1% w/v Nasal Spray, Solution
Otrivine Blocked Nose Relief, 0.1% w/v Nasal Spray, Solution
Otrivine Allergy Relief, 0.1% Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: 0.1% *wlv* Xylometazoline Hydrochloride

For excipients see 6.1

3 PHARMACEUTICAL FORM

Nasal spray, solution (Nasal Spray)

A clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of nasal congestion, perennial and allergic rhinitis (including hay fever), sinusitis.

4.2 Posology and method of administration

Adults and elderly: One application in each nostril up to 3 times daily. Do not exceed 3 applications daily into each nostril.

Not suitable for children under 12 years.

Route of administration: Application to the nasal passages.

Laterally actuated pump (Khone): The laterally actuated metered-dose spray ensures that the solution is well distributed over the surface of the nasal mucosa by spraying a fine mist.

Before using for the first time, prime the pump by actuating 5 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be re-primed with 2 actuations.

Vertically actuated pump (Freepod): Before the first application, prime the pump by actuating 4 times. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be reprimed with 4 actuations.

The recommended dose should not be exceeded, especially in children and the elderly.

4.3 Contraindications

Known hypersensitivity to xylometazoline.

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

Narrow-angle glaucoma.

Rhinitis sicca or atrophic rhinitis.

Otrivine 0.1% is contraindicated in children aged less than 12 years.

Use in people with phaeochromocytoma, prostatic hypertrophy or those 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.

Otrivine, 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, diabetes mellitus or tri and tetra-cyclic antidepressant treatment (see Interactions).

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

Keep medicines out of the sight and reach of children.

Information concerning excipients

Otrivine contains benzalkonium chloride. This may cause irritation of the nasal mucosa.

4.5 Interaction with other medicinal products and other forms of interaction

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

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 Otrivine 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 Otrivine should be used only on the advice of a doctor whilst breastfeeding.

4.7 Effects on ability to drive and use machines

Otrivine 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
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

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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store.

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

Otrivine Adult Measured Dose Sinusitis Spray 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 Otrivine Adult Measured Dose Sinusitis Spray begins within a few minutes and lasts for up to 10 hours. Otrivine Adult Measured Dose Sinusitis Spray is generally well tolerated and does not impair the function of ciliated epithelium.

In a double-blind, saline solution (Otrisal) controlled study in patients with common cold, the decongestant effect of Otrivine was significantly superior ($p<0.0001$) to Otrisal saline solution based on rhinomanometry measurement at 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

Disodium phosphate dodecahydrate (Sodium phosphate)

Disodium edetate

Sodium dihydrogen phosphate dihydrate (Sodium acid phosphate)

Sodium chloride

Sorbitol

Hypromellose

Purified water

6.2 Incompatibilities

None

6.3 Shelf life

36 months

After first opening, the nasal spray can be used until the end of the shelf-life.

6.4 Special precautions for storage

Freepod: No special precautions.

Khone: Do not store above 30°C.

6.5 Nature and contents of container

High density polyethylene bottle with a vertically actuated polypropylene/polyethylene metered dose pump (materials in contact with the solution: low density polyethylene, high density polyethylene, polyethylene/butyl, stainless steel) and a polypropylene nozzle with a protective cap in a cardboard carton.

Or

High density polyethylene bottle with a laterally actuated metered dose pump (materials in contact with product: low density polyethylene/polyethylene compound, lubricant, stainless steel, polydimethyl-siloxane, PTFE/PET layer) with a polypropylene nozzle with protective cap.

Pack size 10 ml.

6.6 Special precautions for disposal

Medicines should be kept out of the reach of children.

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited

The Heights

Weybridge

Surrey

KT13 0NY

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0184

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27/02/2024