SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Otrivine Congestion Relief 0.1% Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Otrivine Congestion Relief 0.1% Nasal Spray, nasal solution contains 1 mg/ml of xylometazoline hydrochloride. Each metered-dose spray delivers 0.14 mg of xylometazoline hydrochloride.

Excipients with known effect: polyoxyl hydrogenated castor oil (2.750 mg/ml)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, (solution)

Metered-dose spray: opalescent, white solution, with menthol and eucalyptol (cineole) odour.

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

Otrivine Congestion Relief 0.1% Nasal Spray should not be used in children aged less than 12 years old.

Adults and children over 12 years: One application in each nostril up to 3 times daily as needed.

Do not exceed 3 applications daily into each nostril.

Route of administration: Nasal use

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.

If the full spray is not administered, the dose should not be repeated.

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

4.3 Contraindications

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

Like other vasoconstrictors, Otrivine Congestion Relief 0.1% Nasal Spray should not be used in patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater, Narrow-angle glaucoma, rhinitis sicca or atrophic rhinitis.

Use in people with phaeochromocytoma, prostatic hypertrophy or those receiving monoamine oxidase inhibitors (MAOI) treatment or who have used them in the last two weeks.

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

4.4 Special warnings and precautions for use

Otrivine Congestion Relief 0.1% Nasal Spray should not be used for more than seven consecutive days, prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Otrivine Congestion Relief 0.1% Nasal Spray, like other sympathomimetic agents, should be used with caution in patients showing a strong reaction to adrenergic substances, as manifested 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 or tri and tetra-cyclic antidepressants (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
This medicine contains polyoxyl hydrogenated castor oil (2.750 mg/ml) which may cause skin reactions.

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 Congestion Relief 0.1% Nasal Spray 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

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

Pharmacotherapeutic group: decongestants for topical use, sympathomimetics, plain.

ATC Code: R01A A07

Mechanism of action and pharmacodynamic effects

Xylometazoline is a sympathomimetic agent acting on alpha-adrenergic receptors in the nasal mucosa. Administered in the nose, it constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This decongests nasal passages and enables patients suffering from blocked nose to breathe more easily through the nose. The effect of Otrivine begins within a few minutes and lasts for up to 10 hours.

In a double-blind, saline solution controlled study in patients with common cold, the decongestant effect of Otrivine 0.1% nasal solution was significantly superior ($p<0.0001$) to saline solution based on rhinomanometry measurement. Relief of blocked nose developed twice as fast in the Otrivine group compared to saline solution as of 5 minutes post treatment ($p= 0.047$).

Otrivine is well tolerated, even by patients with a sensitive mucosa, and does not impair the mucociliary function.

5.2 Pharmacokinetic properties

Plasma concentrations of xylometazoline in man after local nasal application of the product are very low and close to the limit of detection.

5.3 Preclinical safety data

Xylometazoline has no mutagenic effect. No teratogenic effects were shown in a study where xylometazoline was given subcutaneously in mice and rats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate dihydrate

Disodium phosphate dodecahydrate

Sodium chloride

Disodium edetate

Levomenthol

Cineole

Sorbitol

Polyoxyl hydrogenated castor oil (macrogol glycerol hydroxystearate)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months

Do not use the bottle for more than 28 days after opening.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package.

6.5 Nature and contents of container

High density polyethylene bottle with a metered dose pump (materials in contact with product: low density polyethylene, stainless steel, compound PE/butyl) polypropylene nozzle with cap.

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.

Content: 10 ml.

6.6 Special precautions for disposal

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
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KT13 0NY
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8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0151

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/02/2025

10 DATE OF REVISION OF THE TEXT

18/02/2025