Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 1mg xylometazoline hydrochloride equivalent to 0.1 % w/v.

Excipients: Benzalkonium chloride 0.1mg/ml.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution (nasal spray).

A clear, colourless, virtually odourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a nasal decongestant for relief of the symptoms of acute rhinitis in allergic or upper respiratory tract infections, including the common cold or influenza. Relief of sinusitis.

4.2 Posology and method of administration

Otrivine should not be used for more than seven consecutive days (see section 4.4).

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

Adults (including the elderly) and adolescents over 12 years of age:

1 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.

Paediatric population:

Otrivine Nasal Spray should not be used in aged less than 12 years old.

Route of administration: Nasal use.

1. Blow the nose gently.
2. Remove protective cap.
3. Do not cut the nozzle. The metered dose spray is ready to prime before use.
4. Before the first application, prime the pump by actuating (depressing the pump) 4 times. Once primed the pump will normally remain charged throughout regular daily treatment periods. Should the spray not be ejected during the full actuation, the pump will need to be re-primed by actuating 4 times. Be very careful not to spray in the eyes or mouth.
5. Hold the bottle upright with thumb under base and nozzle between two fingers.
6. Lean forward slightly and insert the nozzle into the nostril.
7. Spray and breathe in gently through the nose at the same time.
8. Repeat with the other nostril.
9. Clean and dry the nozzle before replacing back the cap right after use.

4.3 Contraindications

Hypersensitivity to xylometazoline or to any of the excipients (see list in section 6.1).

Otrivine nasal spray should not be used in patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.

Patients with acute coronary disease, hyperthyroidism or narrow angle glaucoma.

Rhinitis sicca and Atrophic rhinitis.

Use in patients who are receiving monoamine oxidase inhibitors, or within 14 days of stopping such treatments.

Otrivine Nasal Spray is contraindicated in children aged less than 12 years old.

4.4 Special warnings and precautions for use

Otrivine nasal spray, like other sympathomimetic agents, should be used only 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.

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 seven consecutive days. Prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Do not exceed the recommended dose, especially in children and in the elderly.

Otrivine nasal spray should be used with caution in patients with: hypertension, cardiovascular disease, diabetes mellitus, phaeochromocytoma, prostatic hypertrophy, and in patients on tri and tetra-cyclic antidepressant treatment (see section 4.5).

Keep out of the sight and reach of children.

For prevention of cross infection, it is recommended that each product package is used by one person only.

Paediatric population
Otrivine Nasal Spray should not be used in children aged less than 12 years old.

Information concerning excipients
Otrivine Nasal Spray contains benzalkonium chloride which may cause irritation or swelling inside the nose, especially if used for a long time.

4.5 Interaction with other medicinal products and other forms of interaction

This product may alter the effects of some anti-hypertensives, such as beta-blockers, and of some anti-depressants, such as monoamine oxidase inhibitors (MAOIs), tricyclic and tetracyclic anti-depressants.

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

Monoamine oxidase inhibitors (MAO inhibitors): xylometazoline may potentiate the action of monoamine oxidase inhibitors and may induce hypertensive crisis. Xylometazoline is not recommended in patients who are taking or have taken MAOIs within the past two weeks (see section 4.3).

Tri- and tetra-cyclic antidepressants: concomitant use of tri- or tetra cyclic antidepressants and sympathomimetic preparations may result in an increased sympathomimetic effect of xylometazoline and is therefore not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy:

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.

Breastfeeding:

There is 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 only be used under medical advice, whilst breastfeeding.

Fertility:

There are no adequate data for the effects of Otrivine on fertility and no animal studies are available. As the systemic exposure to xylometazoline hydrochloride is very low, effects on fertility are therefore very unlikely.

4.7 Effects on ability to drive and use machines

Otrivine Nasal Spray has no or negligible influence on the ability to drive or 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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Overdose of oral or excessive administration of topical xylometazoline hydrochloride 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.

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 may include observation of the individual for at least several hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC Code: RO1A A07.

Mechanism of action and pharmacodynamic effects:

Otrivine Nasal 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. It also reduces associated symptoms of mucus hypersecretion and facilitates drainage of blocked secretions. This enables patients suffering from colds to breathe more easily through the nose.

The effect of Otrivine begins within a few minutes and lasts upto 10 hours. Otrivine Spray is generally well tolerated and does not impair the function of ciliated epithelium.

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.

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
Liquid Sorbitol (non-crystallising) (E420)
Hypromellose
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

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

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

High density polyethylene bottle with a 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.

Pack size 10 ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
12 Riverwalk
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8 MARKETING AUTHORISATION NUMBER

PA0678/120/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 February 1991

Date of last renewal: 27 February 2006

10 DATE OF REVISION OF THE TEXT

November 2023