Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Otrivine Congestion Relief Menthol 0.1% w/v Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray 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 relief of nasal congestion due to colds, hay fever or other allergic rhinitis, sinusitis.

To aid drainage of secretions in affections of the paranasal sinuses.

As an adjuvant in otitis media, to decongest the nasopharyngeal mucosa.

To facilitate rhinoscopy.

Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray is indicated in adults and in adolescents over 12 years of age.

4.2 Posology and method of administration

Posology

Paediatric population

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

Method of administration

Otrivine Nasal Spray nasal metered-dose spray

Strength	Age	Posology
0.1%	Adults and adolescents over 12 years of age	1 spray into each nostril, 3 times daily as needed. Do not exceed 3 applications daily into each nostril.

The metered-dose spray permits accuracy of dosage and ensures that the solution is well distributed over the surface of the nasal mucosa. It precludes the possibility of unintentional overdose.

Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray should not be used for more than seven consecutive days (see section 4.4).
The recommended dosage should not be exceeded, especially in children and the elderly

Before the first application, 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.

Administration

Remove cap.

Be very careful not to spray in the eyes or mouth.

1. Clear the nose.
2. Hold the bottle with thumb on the actuation button.
3. For a no dripping effect, stay upright and insert the short nozzle into a nostril.
4. Press on the button to spray and breathe in gently through the nose at the same time. Repeat this procedure (steps 2 to 4) in the other nostril.
5. After each use, clean and dry the nozzle and
6. Put the protective cap back on until an audible "click" is heard.

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

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 Menthol, 0.1% w/v 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 0.1% is contraindicated in children aged less than 12 years old.

4.4 Special warnings and precautions for use

Otrivine Congestion Relief Menthol, 0.1% w/v 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.

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

Like other topical vasoconstrictors, Otrivine Congestion Relief Menthol, 0.1% w/v 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.

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

Caution is recommended 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 Congestion Relief Menthol, 0.1% w/v Nasal Spray should not be used in children aged less than 12 years old.

Information concerning excipients
This medicine contains polyoxyl hydrogenated castor oil which may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Like for all sympathomimetics, a reinforcement of the systemic effects of xylometazoline by concomitant use of monoamine oxidase inhibitors, tricyclic or tetracyclic antidepressants, may cause an increase in blood pressure due to the cardiovascular effects of these substances and cannot be excluded, especially in case of overdose.

4.6 Fertility, pregnancy and lactation

Fertility
There are no adequate data for the effects of Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray 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

Pregnancy
In view of its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray 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 Congestion Relief Menthol, 0.1% w/v Nasal Spray should be used only under medical advice, while breast-feeding.

4.7 Effects on ability to drive and use machines

Otrivine Congestion Relief Menthol, 0.1% w/v 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 HPRA Pharmacovigilance, website: www.hpra.ie.

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 noseto breathe more easily through the nose. The effect of Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray 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 Congestion Relief Menthol, 0.1% w/v Nasal Spray is well tolerated, even by patients with a sensitive mucosa, and does not impair the mucociliary function.

Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray contains no preservative. The one-way vacuum pump delivering the metered dose spray is specifically designed to prevent microbial contamination of the content. The nozzle has a special design and a cap with special openings that allow the residual liquid to dry, thus preventing microbial contamination of the next sprayed dose.

Otrivine Congestion Relief Menthol, 0.1% w/v Nasal Spray contains cooling aromatic vapours of menthol and eucalyptol (cineole) in addition to the active ingredient xylometazoline.

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 (Menthol)
Cineole (Eucalyptol)
Sorbitol
Polyoxylhydrogenated castor oil (Macrogol glycerol hydroxystearate)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

10ml high density polyethylene (HDPE) 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.

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

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8 MARKETING AUTHORISATION NUMBER

PA0678/120/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th July 2014

Date of last renewal: 3rd July 2019

10 DATE OF REVISION OF THE TEXT

February 2026