SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Otrivin Menthol (without preservative) 1.0 mg/ml nasal spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 1.0 mg xylometazoline hydrochloride.

For the full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Rhinitis. For decongestion in sinusitis and for facilitating rhinoscopy.

4.2 Posology and method of administration

Adults and children above twelve years of age: One application in each nostril as required 2-3 times daily for a maximum of ten days.

Two fingers vertically actuated pump:

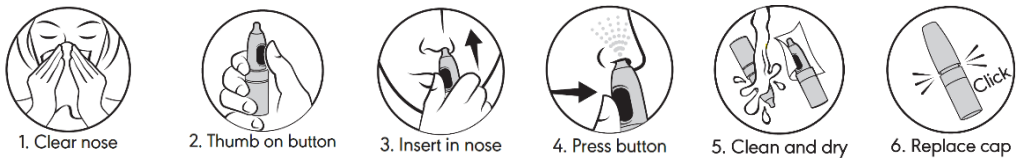
Before the first application, prime the pump by actuating 4 times. Once primed the pump will normally remain charged throughout regular daily treatment periods. Should the spray not be ejected during the full actuation stroke or if the product has not been used for longer than 6 days, the pump will need to be reprimed with 4 actuations as initially performed.

Thumb laterally actuated pump:

Remove the cap.

Before the first use
Prime the pump by actuating 5 times. Once primed the pump will normally remain charged throughout regular daily treatment periods.

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



Should the spray not be 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.

If the full spray is not administered, the dose should not be repeated.
To avoid possible spread of infection, the spray should only be used by one person.
Avoid spraying Otrivin in or around the eyes.

Each metered-dose spray delivers 0.14 ml per actuation (0.14 mg of xylometazoline hydrochloride).

Otrivin Menthol is not recommended for use in children below 12 years of age due to insufficient data on safety (see section 4.4). It is recommended to make the last application shortly before retiring to bed.

4.3 Contraindications

Hypersensitivity to xylometazoline hydrochloride or to menthol or any of the other excipients. Narrow angle glaucoma. After transsphenoidal hypophysectomy or surgery exposing the dura mater. Patients with rhinitis sicca or atrophic rhinitis.

4.4 Special warnings and precautions for use

Otrivin Menthol is to be used with care in patients who are sensitive to adrenergic substances which can cause symptoms such as sleep disturbances, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.

Otrivin should be used with caution in:

- patients with hypertension, cardiovascular disease. Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias
- patients with hyperthyroidism, diabetes mellitus, phaeochromocytoma
- patients with prostatic hypertrophy
- patients treated with monoamine oxidase inhibitors (MAOI) or who have received them in the last two weeks (see section 4.5)
- tri and tetra-cyclic antidepressant treatment (see section 4.5)

Otrivin Menthol should be used for a maximum of ten successive days in order to avoid a rebound effect in form of nasal congestion and drug-induced rhinitis, which may lead to physical drug dependence and/or atrophy of the nasal mucosa.

Instillation of decongestant preparations containing menthol directly into the nostrils of infants and young children must be avoided, as it has resulted in acute respiratory distress with cyanosis and respiration arrest. Do not exceed the recommended dose, especially in children and in the elderly.

Otrivin Menthol should not be used in children aged less than 12 years.

4.5 Interactions with other medicinal products and other forms of interaction

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 4.4).

Tricyclic or tetracyclic 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 Pregnancy and lactation

Pregnancy
In view of its potential systemic vasoconstrictor effect it is advisable to take the precaution of not using Otrivn Menthol during pregnancy.
Lactation
It is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and Otrivin Menthol should be used only under medical advice while breast-feeding.
Fertility
There are no adequate data for the effects of Otrivin 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

Not applicable.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: 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) or not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Immune system disorders:
Not known: Hypersensitivity reaction (angioedema, rash, pruritus)
Nervous system disorders
Common: Headache
Eye disorders
Not known: Visual impairment
Cardiac Disorders
Not known: Heart rate irregular and heart rate increased
Respiratory, thoracic and mediastinal disorders
Common: Nasal dryness or nasal discomfort, burning sensation
Uncommon: Epistaxis
Very rare: Rebound congestion
Gastrointestinal disorders
Common: Nausea
Investigations
Not known: Increased blood pressure

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization 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 national reporting system.

4.9 Overdose

Toxicity: 2.5 mg per os in two- to three-year-old caused mild intoxication. Eight drops 0.1% solution nasally in a nine-month-old infant caused mild intoxication. Three times the adult dose nasally in a one-month-old infant caused moderate to severe intoxication.

Symptoms: Excessive administration of topical xylometazoline hydrochloride or accidental ingestion may cause severe dizziness, perspiration, headache, respiratory depression, coma, seizures, hypothermia, hypertension, peripheral vasoconstriction, cold extremities, bradycardia, mydriasis, bronchospasm and convulsions. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults.

Treatment: Appropriate supportive measures should be initiated under medical supervision in all individuals suspected of an overdose. This would include observation of the individual for several hours. Where necessary, activated charcoal. Monitor respiration and circulation. Oxygen, respirator where necessary. In case of seizure appropriate anticonvulsant therapy such as diazepam.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Decongestant nasal spray. ATC code: R01AA07.

Xylometazoline is a sympathomimetic which acts on the α-adrenergic receptors. It has a vasoconstrictive effect and thus acts as decongestant and facilitates drainage of secretions. Xylometazoline constricts the blood vessels in the nose and so decongests the nasal mucosa and neighboring regions of the pharynx. The effect of Otrivin Menthol begins within a few minutes and lasts for 10 hours.
In vitro assays have shown that xylometazoline reduces the infectious activity of three serotypes of human rhinoviruses associated with the common cold. Clinical relevance of this effect is so far unknown.

5.2 Pharmacokinetic properties

Maximum plasma concentration of xylometazoline in man after local nasal application of the product are very low (in the range of 0.1 ng/ml).

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

Menthol, cineole, disodium edetate, sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, sodium chloride, sorbitol, macrogol glycerol hydroxystearate, purified water.

The contents are free from preservatives.

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

10 ml HDPE bottle mounted with a metered-dose spray pump (materials in contact with the solution: LDPE, HDPE, PE / butyl, stainless steel) and a PP nozzle with a protective cap.
2 different spray pumps are available: a two fingers vertically actuated pump and a thumb laterally actuated pump

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8 MARKETING AUTHORISATION NUMBER

13979

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 March 1998/ 20 March 2008

10 DATE OF REVISION OF THE TEXT

2024-05-30