SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Otrivin **Nasal solution** **Drops** 0.1% w/v	**Otrivin** **Nasal solution** **Spray** 0.1% w/v	**Otrivin** **Nasal solution** **Metered Dose Spray** 0.1% w/v

2. Qualitative and quantitative composition
Active ingredient: 0.1% w/v Xylometazoline Hydrochloride
For excipients see 6.1

3. Pharmaceutical form
Otrivin Nasal Solution Drops
Nasal drops, solution;
A clear, colourless solution

Otrivin Nasal Solution Spray
Nasal spray Solution;
A clear, colourless solution

Otrivin Nasal Solution Metered dose spray
Nasal spray, solution
A clear, colourless solution

4. Clinical particulars
4.1 Therapeutic indications
Rapid relief of nasal congestion for up to ten hours in adults and adolescents aged 12 years and older.

4.2 Posology and method of administration
Otrivin Nasal Solution Drops:
Adults and adolescents over 12 years of age: 2-3 drops in each nostril, every 8-10 hours, as necessary.
Do not exceed a dosage of 3 daily applications in each nostril.
Route of administration: Nasal use

Otrivin Nasal Solution Spray:
Adults and adolescents over 12 years of age: 1 inhalation in each nostril, every 8-10 hours, as necessary.
Do not exceed 3 daily applications in each nostril.
Route of administration: Nasal use

Otrivin Nasal Solution Metered dose spray:
Adults and adolescents over 12 years of age: 1 inhalation in each nostril, every 8-10 hours, as necessary.
Do not exceed 3 daily applications in each nostril.
Route of administration: Application to the nasal passages.

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.
Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.
Narrow-angle glaucoma
Rhinitis sicca or atrophic rhinitis.
Otrivin 0.1%w/v is contraindicated in children aged less than 12 years
People with phaeochromocytoma or prostatic hypertrophy or 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 three consecutive days. Prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa. Otrivin, 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, or 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
Otrivin contains Benzalkonium chloride in each unit which is equivalent to 0.100 mg/ml.
Otrivin Drops 0.0025mg.
Otrivin Meter dose spray 0.014mg.
Otrivin Spray accurate dosage cannot be given as depend the usage.

Benzalkonium chloride 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
The concomitant use of xylometazoline with monoamine oxidase (MAO) inhibitors, or tricyclic and tetracyclic 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 Otrivin 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 Otrivin should be used only on the advice of a doctor whilst breastfeeding.

4.7 Effects on ability to drive and use machines
Otrivin 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 Apnoea in young infants and newborns	Common Common Uncommon Very rare
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 suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
/https://sideeffects.health.gov.il

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

Otrivin 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 neighboring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Otrivin begins within a few minutes and lasts for up to 10 hours. Otrivin 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 Otrivin 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

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol 70%
Methylhydroxypropylcellulose 4000 mPa.s

Sodium dihydrogen phosphate dihydrate
Sodium chloride
Disodium phosphate dodecahydrate
Disodium edetate
Benzalkonium chloride
Purified water

6.2 Incompatibilities
None

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage
Store below 30ºC, in the original package

6.5 Nature and contents of container
Otrivin Drops
High density polyethylene bottle with a low density polyethylene pipette with halogenated butyl elastomer bulb and polyethylene guarantee cap.

Otrivin Spray
Squeeze bottle of high density polyethylene and polypropylene fitted with a low density polyethylene nozzle (nebulizer). The nozzle is fitted with a low density polyethylene dip tube and protected by a high density polyethylene guarantee cap.

Otrivin Nasal Dosing Spray
High density polyethylene bottle for crimping with Propylene nose piece metered dose pump including an actuator mounted with a polyethylene protective cup.
Pack size: 10 ml

6.6 Special precautions for disposal and other handling
Keep all medicines out of the reach of children

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9. Marketing authorisation number
115-43-22229-00

Revised in March 2024