Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Otrivin Kids

Xylometazoline hydrochloride 0.5 mg/mL
Nasal spray, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL of solution contains 0.5 mg xylometazoline hydrochloride.
1 spray of 0.07 mL solution contains 0.035 mg xylometazoline hydrochloride.

1 drop 0.025 mL solution contains 0.013 mg xylometazoline hydrochloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal, solution.
Clear, colorless and practically odourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

4.2 Rapid symptomatic relief of nasal decongestion up to 10 hours in children aged 2-12 years Posology and method of administration

Otrivin Kids should not be used in children younger than 2 years of age. In children aged 2 to 12 years, the medicine should only be used under adult supervision.

Dosage
Otrivin Metered-dose spray:
Children aged 2-12 years: 1 spray in each nostril up to 3 times a day (every 8 to 10 hours).

Otrivin Drops:
Children aged 2-12 years: 2-3 drops in each nostril up to 3 times a day (every 8 to 10 hours).

Do not exceed 3 applications per nostril in 24 hours.
Otrivin Kids Otrivin Kids should not be used for longer than 3 days. Do not exceed the recommended dosage, particularly in children and the elderly.

Method of administration
For use in the nose.

Metered dose Spray
Remove the protective cap.
The metered-dose spray is ready to use. Therefore **DO NOT** cut off the tip!

Before using the spray for the first time the pump must be primed by actuating it 4 times. Once filled, the pump generally remains ready to use when used regularly on a daily basis. If the spray is not ejected during the full actuation stroke, or if the medicine has not been used for more than 7 days, the pump must be reprimed with 2 actuations.

Avoid spraying in eyes
1. Prior to use, blow your child's nose thoroughly.
2. Keep the bottle upright and use your forefinger and middle finger to spray while supporting the base of the bottle with your thumb.
3. Tilt your head forward slightly and carefully insert the nasal applicator into the nostril.
4. Press down on the applicator to release the spray once and inhale gently through the nose at the same time.
5. Repeat the steps with the other nostril.
6. After each use, wipe the applicator with a clean cloth and replace the protective cap.

If possible, apply the last dose of the day before going to bed.
For sanitary reasons and to avoid infections, please note that each dosing unit may only be used by one patient.

Nasal Drops
1. Blow your child's nose.
2. Before use, prepare the pipette to obtain a uniform distribution of the dose.
3. Tilt your child's head backwards) see Figure A).
4. Without touching the nose, drop Otrivin Kids very carefully into your child's nostril. Keep your child's head tilted back for several minutes to allow the drops to absorb into the nose.
5. If the drop doesn't reach your child's nostril, use another drop.
6. Do not drip another drop if part of the drop enters your child's nostril.
7. Repeat the steps with the other nostril.
8. Clean and dry the dropper before replacing it in the bottle.
9. To prevent the spread of infection, this pack is intended to be used by one person only.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- S/P transsphenoidal hypophysectomy or other surgical procedures that expose the dura
- Patients with narrow-angle glaucoma
- Dry inflammation of the nasal mucosa (rhinitis sicca or atrophic rhinitis)
- Children aged less than 2 years

4.4 Special warnings and precautions for use

As a sympathomimetic, Otrivin Kids should be used with caution in patients with a strong reaction to adrenergic substances, which can be manifested by insomnia, dizziness, tremor, cardiac arrhythmia and/or arterial hypertension.

Otrivin Kids should always be used with caution in patients with:
- hypertension, cardiovascular diseases
- hyperthyroidism, diabetes mellitus, pheochromocytoma
- prostatic hyperplasia
- patients currently taking monoamine oxidase inhibitors or those who have taken them in the last two weeks (see section 4.5)
- patients taking tricyclic and tetracyclic antidepressants (see section 4.5).

Patients with long QT syndrome receiving treatment with xylometazoline may be at increased risk of severe ventricular arrhythmias.

As a topical vasoconstrictor, Otrivin Kids should not be used for more than 3 days. Long-term use or excessive use may lead to chronic swelling (rhinitis medicamentosa) and/or atrophy of the nasal mucosa.

Children and adolescents
Otrivin Kids should not be used in children younger than 2 years of age. In children aged 2 to 12 years, it should be used under adult supervision.

Information concerning excipients
Otrivin Kids contains Benzalkonium chloride in each unit which is equivalent to 0.100 mg/ml.
Otrivin Kids Drops 0.0025mg.
Otrivin Kids Meter dose spray 0.007mg.

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

Using xylometazoline in combination with monoamine oxidase inhibitors (MAOIs) or tricyclic and tetracyclic antidepressants may lead to an increase in blood pressure due to the cardiovascular effects of these substances (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
To date, there is no or only very limited experience (less than 300 pregnancy outcomes) with the use of xylometazoline in pregnant women.
Animal studies have demonstrated reproductive toxicity (see section 5.3).

In view of a potential systemic vasoconstrictor effect, it is not recommended to use Otrivin Kids during pregnancy.

Lactation
Otrivin Kids should not be used during breastfeeding because it is not known whether or not the active substance xylometazoline passes into human breast milk.

Fertility
There is insufficient data on the effects of xylometazoline on human fertility .

4.7 Effects on ability to drive and use machines

Otrivin Kids has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following frequency convention is used for categorizing undesirable effects:

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)
Not known	(Frequency cannot be estimated based on available data)

Immune system disorders
Very rare: Hypersensitivity reactions (angioedema, eczema, pruritus)

Nervous system disorders
Common: Headache

Very rare: Restlessness, insomnia, fatigue (drowsiness, sedation), hallucinations (primarily in children)

Eye disorders
Very rare: Transient visual disturbances.

Cardiac disorders
Rare: Palpitations, tachycardia, arterial hypertension
Very rare: Irregular heart rate, increased heart rate

Respiratory, thoracic and mediastinal disorders
Common: Dry nasal mucosa, nasal symptoms, sneezing
Uncommon: Increased mucosal swelling after the effect has worn off, epistaxis (nosebleeds).
Very rare: Apnea in young infants and newborns

Gastrointestinal disorders
Common: Nausea

Musculoskeletal and connective tissue disorders
Very rare: Convulsions (especially in children)

General disorders and administration site conditions
Common: Burning sensation at the application site.

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

The clinical picture of intoxication with imidazole derivatives can be puzzling, as phases of CNS and cardiovascular system stimulation can alternate with phases of CNS and cardiovascular system suppression.
Symptoms of CNS stimulation include anxiety, agitation, hallucinations and convulsions.
Symptoms resulting from inhibition of the central nervous system include a drop in body temperature, lethargy, drowsiness and coma.

The following symptoms may also occur:
Miosis, mydriasis, profuse sweating, fever, pallor, cyanosis, nausea, tachycardia, bradycardia, cardiac arrhythmia, cardiac arrest, hypertension, shock-like hypotension, pulmonary edema, respiratory dysfunction and apnea.

Particularly in children, overdose often leads to prominent central nervous system effects such as convulsions and coma, bradycardia, apnea as well as arterial hypertension, which may be followed by hypotension.

Therapeutic measures in case of overdose
If an overdose is suspected, appropriate supportive measures should be initiated. Acute symptomatic treatment under medical supervision may sometimes be required. This involves monitoring the patient for several hours.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Rhinologics – decongestants and other nasal preparations for topical use - Sympathomimetics, pure
ATC code: R01AA07

Mechanism of action
Xylometazoline hydrochloride is a sympathomimetic agent acting on alpha-adrenergic receptors in the nasal mucosa. When administered in the nose, it causes the nasal blood vessels to constrict. This leads to decongestion of the nasal mucosa and the adjacent pharyngeal tissue.
It also alleviates the symptoms associated with mucus hypersecretion and promotes drainage of secretions from a blocked nose. As a result of the reduced swelling of the nasal mucosa, patients with nasal congestion can breathe more easily through the nose.

Pharmacodynamic effects
The onset of action of Otrivin Kids is within 2 minutes and it lasts for several hours (on average 6–8 hours).

The pH of Otrivin Kids matches the pH range of the nasal cavity.

5.2 Pharmacokinetic properties

Following topical nasal administration of xylometazoline to humans, plasma concentrations are very low.

Absorption
There is minimal systemic absorption after topical application. However, if the recommended dose is exceeded, intranasal xylometazoline may nevertheless be absorbed with resulting systemic sympathomimetic side effects (see section 4.4).

Distribution
There are no data from studies in humans.

Biotransformation
There are no data from studies in humans.

Elimination
There are no data from studies in humans.

Special patient populations
No studies were conducted on special patient populations.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity.

Carcinogenicity and genotoxicity
No data on carcinogenicity are available for xylometazoline. The *in-vitro* and *in-vivo* data on genotoxicity, however, do not indicate a genotoxic potential.

Reproductive toxicology
No teratogenic effects of xylometazoline were observed in mice, rats and rabbits.
Doses above therapeutic levels were embryo-lethal or resulted in impaired fetal growth.
Milk production was inhibited in rats. There is no evidence of impaired fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water; Sorbitol 70% (noncrystallising);Methylhydroxypropylcellulose 4000mPa s;Sodium dihydrogen phosphate dihydrate; Sodium chloride; Disodium phosphate dodecahydrate; Disodium edetate; Benzalkonium chloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Store Below 30°C.

6.5 Nature and contents of container

Metered dose spray
Plastic bottle (HDPE) mounted with a snap-on metered-dose pump including an actuator and mounted with protective cap.
10ml

Drops
Plastic (HDPE) Bottle.
10ml

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

Haleon CH, Israel, Ltd.
P.O.B 3256, Petach Tikva, 4951038, Israel

8. MANUFACTURER

Haleon CH SARL,
Route De I'etraz 1260 Nyon, Switzerland

9. MARKETING AUTHORIZATION NUMBER

108-21-23658-00
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