SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OTRIVIN NASAL DROP 0.05% CHILD

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: xylometazoline hydrochloride 0.05% w/v

OTRIVIN NASAL DROP 0.05% CHILD 1 drop contains 0.0125 mg xylometazoline hydrochloride.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal Drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OTRIVIN NASAL DROP 0.05% CHILD is indicated for children between 2-11 years under adult supervision.

Used for:

- Various types of head cold
- For easing the flow of mucus in inflammations of the nasal sinuses.
- For otitis media as an adjunct for decongestion in the nasopharyngeal area.
- For easing of rhinoscopy.

4.2 Posology and method of administration

Posology

Pediatric population

Children aged 2-11 years normally, 1–2 drops of the 0.05% solution
1–2x daily You must not exceed 3 applications per day.

Children aged 1-2 years: use according to the doctor's prescription.

The safety and efficacy of Otrivin Nasal Drops in children aged 0-12 months have not been established.

The last application of the day should preferably be shortly before going to bed.

Otrivin Nasal Drops should not be used for longer than 1 week as longer-term use can lead to Rhinitis medicamentosa

How to use the drops:

Clean (blow) the nose thoroughly before use.

Tilt the head back slightly. Insert the drops into each nostril and briefly keep the head tilted back so

that the drops can spread out. Clean and dry the dropper before screwing it back onto the bottle. Method of administration
Intranasal.

4.3 Contraindications

Otrivin Nasal Drops are contraindicated in:

— Cases of known hypersensitivity to the Xylometazoline HCl or to any of the excipients used.

— Patients with history and progression of trans-sphenoid hypophysectomy (or after trans-nasal or trans-oral surgeries which expose the dura mater) or
for dry nasal mucosa (Rhinitis sicca), atrophic rhinitis, closed angle glaucoma.

4.4 Special warnings and precautions for use

Otrivin nasal drops should be used with caution in patients:

- with high blood pressure, cardiovascular disorders, Patients with a long QT syndrome have an increased risk of severe ventricular arrhythmia when undergoing treatment with xylometazoline.
- with hyperthyreosis, diabetes mellitus, phaeochromocytoma,
- with prostatic hypertrophy,
- who are being treated with MAO inhibitors or who have received these within the last 14 days (see "Interactions"),
- with intensified reactions to sympathomimetic substances with signs of insomnia, light headedness, etc.

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As with other topical vasoconstrictors, ongoing treatment with Otrivin Drops lasting longer than 1 week is not indicated as Rhinitis medicamentosa with nasal mucosal swelling can occur; this has very similar symptoms to a head cold.
The recommended dose should not be exceeded, especially in children and elderly patients. Otrivin/Otrivine drops 0.05% (nasal drops and metered-dose spray) should not be used by children aged under 1 year. For children aged from 1 to 2 years, use only according to the doctor's prescription. For children aged from 2 to 11 years, use only under adult supervision.

4.5 Interaction with other medicinal products and other forms of interaction

MAO inhibitors: xylometazoline can intensify the effect of MAO inhibitors and cause a hypertensive crisis. Xylometazoline is not recommended for patients who are taking MAO inhibitors, or who have taken one within the last 14 days (see "Warnings and precautions").
Tri- or tetra-cyclic antidepressants: the concurrent administration of tricyclic or tetracyclic antidepressants with sympathomimetics can lead to intensification of the sympathomimetic effect of xylometazoline and is therefore not recommended**.**

4.6 Pregnancy and lactation

Pregnancy*:* As a precaution, Otrivin Nasal drops should not be used during pregnancy due to its vasoconstrictive properties.

Lactation: It is unknown whether xylometazoline/ its metabolites are excreted in human milk. Otrivin Nasal drops should only be used on medical advice during lactation.

Fertility: there is no relevant data regarding the effect of Otrivin Nasal drops on fertility and no controlled studies in animals are available. As the systemic exposure of xylometazoline is very low, effects on fertility are unlikely.

4.7 Effects on ability to drive and use machines

Otrivin Nasal Drops have influence on the ability to drive and use machines. This is especially for longer-term application or higher doses of xylometazoline.

4.8 Undesirable effects

The undesirable effects are listed below according to system class and frequency. The
frequencies are defined as follows: 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) and not known (cannot be estimated from the available data)

The undesirable effects are listed in decreasing order of severity within each frequency group. Immune system disorders:

Very rare: hypersensitivity reactions (angio-oedema, rash, pruritus).

Nervous system disorders:
Common: headaches.

Eye disorders:
Very rare: temporary visual disturbances.

Cardiac disorders:
Very rare: irregular and increased heart rate, hypertension, arrhythmias.

Respiratory tracts, thoracic and mediastinal disorders:
Common: nose dryness, nasal discomfort, burning sensation, Rhinitis medicamentosa.

Gastrointestinal disorders:
Common: nausea.

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

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 to National regulatory bodies.

4.9 Overdose

Excessive use of topical xylometazoline or accidental ingestion can cause sympatholytic effects, including CNS depression (such as drowsiness, coma), hypertension by or hypotension, as well as tachycardia and bradycardia. Gastrointestinal symptoms such as nausea and vomiting can also occur. Further symptoms include paleness, excessive sweating, hypothermia, miosis, respiratory depression, ataxia and restlessness.
Severe symptoms after accidental exposure have not been observed; however, in a newborn (2 weeks old) the use of 1 drop of 0.1% solution in each nostril led to a coma.

In infants, the ingestion of up to 0.5 mg/kg body weight did not lead to clinically relevant symptoms. Owing to a lack of data, severe symptoms following the ingestion of more than 0.5 mg/kg body weight cannot be excluded. In such cases, medical monitoring and administration of a single dose of activated charcoal is indicated after consultation with an experienced clinician or a toxicological information center. There is no specific antidote. The therapy is symptomatic; bradycardia can be treated with atropine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nasal Decongestant ATC code: R01AA07

Mechanism of action

Xylometazoline is a sympathomimetic and acts on the alpha-adrenergic receptors in the nasal mucosa.

After application in the nose, the blood vessels are constricted which decreases the swelling in the nasal mucosa and the neighboring areas of the pharynx. This eases nasal breathing.

Furthermore, Otrivin Nasal drops contain ingredients (sorbitol solution and ethyl hydroxypropyl cellulose) intended to prevent the drying of the nasal mucosa. The effect begins within minutes and lasts for up to 12 hours. Otrivin Nasal Drops do not affect the function of the ciliated epithelium.

Pharmacodynamic effects- See mechanism of action.

5.2 Pharmacokinetic properties

After nasal application, the plasma concentrations of xylometazoline in humans are generally low and close to the limit of detection.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium hydrogen phosphate
Sodium dihydrogen phosphate,
Disodium edetate,
Sodium chloride,
Sorbitol
Methylhydroxypropylcellulose
Water
Preservative: benzalkonium chloride.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months
The drug may only be used up to the date indicated with "EXP" on the pack.

6.4 Special precautions for storage

Store below 30 °C.
Keep out of reach of children.

6.5 Nature and contents of container

Available in a 10ml bottle
The bottles are HDPE bottle with a polypropylene cap including a low-density polyethylene pipette
The bottle and patient information leaflet are packed in a carton.

6.6 Special precautions for disposal <and other handling>

No special requirements.

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

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Manufacturing site :
Haleon CH SARL, Route de I'Etraz 1260 Nyon, Switzerland

MAH:
Haleon Kenya Limited
P.O Box 78392-00507,
Nairobi, Kenya

8. MARKETING AUTHORISATION NUMBER

H2007/2197

9. DATE OF FIRST AUTHORIATION OR RENEWAL

15th December 2010

10. DATE OF REVISION OF THE TEXT

26/01/2026