

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Otrivin Moisturising Paediatric Nasal Drops

Generic Name: Xylometazoline Hydrochloride and Sorbitol Nasal Drops I.P.

2. Qualitative & Quantitative Composition

Contains:

Xylometazoline HCl I.P..... 0.05% w/v

Sorbitol Solution (70 %) I.P. ... 2.0% w/v

(Non-Crystallising)

In an aqueous buffered vehicle containing Hydroxypropyl Methylcellulose

Preservative:

Benzalkonium Chloride IP..... 0.01% w/v

3. Dosage Form

Nasal Drops

4. Clinical Particulars

4.1. Uses/ Indications

As nasal decongestant. For the relief of blocked nose caused by colds, hay fever or other allergic rhinitis, sinusitis.

4.2. Posology and method of administration

Otrivin Moisturising Paediatric is indicated in children aged 1 to 11 years old only under adult supervision. Otrivin Moisturising Paediatric Nasal Drops is to be used as nasal drops only. The dose is as follows

Children 1 to 5 years of age- 1 to 2 drops into each nostril, once or twice daily (every 8 to 10 hours), with adult supervision.

Children 6 to 11 years of age- 2 to 4 drops into each nostril, 2 to 3 times daily as needed, with adult supervision.

Do not exceed 3 applications daily into each nostril. It is recommended to make the last application shortly before retiring to bed. Otrivin Moisturising Paediatric should not be used for more than 10 consecutive days. If symptoms persist, consult your doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

Instructions to administer Otrivin Moisturising are as below -

1. Clear the nose.
2. Before using, practice using the dropper to develop good dosage control.

3. Tilt the child's back as far as is comfortable or, if lying on a bed, hang the head over the side.
4. Without touching the dropper to the nose, apply the drops into each nostril and keep the head tilted back for a short time to allow the drops to spread throughout the nose.
5. If the drop completely misses the nose, administer the drop again.
6. If any part of the drop gets into the nose, do not administer the drop again.
7. Repeat with the other nostril.
8. Clean and dry the dropper before replacing it back into the bottle right after use.
9. To avoid possible spread of infection, the bottle should only be used by one person.

4.3. Contra-indications

Otrivin Moisturising Paediatric Nasal Drops should not be used if:

- Child is below 1 year of age.
- Child is allergic to xylometazoline or any other ingredients of this medicine
- Child has undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- Child is suffering from narrow angle glaucoma (increased pressure in eyes)
- Child has chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis).

4.4. Warnings and Precautions

Otrivin Moisturising Paediatric, like other sympathomimetic agents, should be used with caution in children showing a strong reaction to adrenergic substances, as manifested by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure. Consult your doctor if such signs prove troublesome.

Otrivin Moisturising should be used with caution in case of any of the below mentioned condition/s:

- Hypertension, cardiovascular disease
- Hyperthyroidism, diabetes mellitus, phaeochromocytoma
- Prostatic hypertrophy
- Taking or have taken monoamine oxidase inhibitors (MAOI) in the last two weeks
Or taking tri-cyclic and tetra-cyclic antidepressants.

In case suffering from any of the above-mentioned condition/s, please consult your doctor before using Xylometazoline nasal drops.
Do not exceed the recommended dose.

4.5. Interaction with other medicaments and other forms of interaction

Monoamine oxidase inhibitors (MAO inhibitors): Xylometazoline may potentiate the action of monoamine oxidase inhibitors and may induce hypertensive crisis. Hence Otrivin Moisturising is not recommended in patients who are taking or have taken MAOIs within the past two weeks.

Tri- and tetra-cyclic 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, Otrivin Moisturising is not advisable for use 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 Otrivin Moisturising should be used only under medical advice, while breast-feeding.

4.7. Effects on ability to drive and use machines, if contra-indicated

Otrivin Moisturising has no or negligible influence on the ability to drive and use medicines.

4.8. Undesirable effects/side effects

Stop taking Otrivin Moisturising Paediatric and tell your doctor immediately if you experience:

- Common (may affect up to 1 in 10 people) side effects, which include: dryness or irritation of the nasal mucosa, nausea, headache, local burning sensation,
- Very rare (may affect up to 1 in 10,000 people) side effects, which include: Allergic reactions (difficulty breathing or swallowing, swelling of the face, lips, tongue or throat), blurred vision, irregular or fast heartbeat.

Like other products for the relief of blocked nose, Otrivin Moisturising Paediatric may give rise to sleep disturbances, dizziness, tremor in very sensitive patients. Consult your doctor if such signs prove troublesome.

4.9. Overdose

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. In case of accidental ingestion/ overdose, contact your doctor immediately.

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.

If you forget to use Otrivin Moisturising Paediatric, do not take a double dose to make up for a forgotten one.

5. Pharmacological Properties

5.1. Pharmacodynamic Properties & mechanism of action

Pharmacotherapeutic group: nasal decongestants for topical use, sympathomimetics.

Mechanism of Action

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 neighboring regions of the pharynx. It also reduces associated symptoms of mucus hypersecretion and facilitates drainage of blocked secretions. This decongests nasal passages and enables patients suffering from blocked nose to breathe more easily through the nose.

Pharmacodynamics effects:

The effect of Otrivin Moisturising begins within 2 minutes and lasts for up to 12 hours (e.g. all night).

In vitro assays have shown that xylometazoline hydrochloride reduces the infectious activity of human rhinoviruses associated with the common cold.

Otrivin Moisturising Paediatric have a balanced pH within the range found in the nasal cavity. It contains Sorbitol, which is a hygroscopic agent/soothing agent that helps prevent dryness and irritation of the nasal mucosa.

Otrivin Moisturising is well tolerated, even by patients with a sensitive mucosa, and does not impair the mucociliary function.

5.2. Pharmacokinetics

Plasma concentrations of xylometazoline in man after local nasal application of the product are very low and close to the limit of detection.

Absorption: Local administration leads to minimal systemic absorption. Nevertheless, systemic absorption of intranasal xylometazoline occurs and may

lead to systemic sympathomimetic side effects when the recommended doses are exceeded (*see Warnings and Precautions*).

Distribution: There are no data from human studies.

Metabolism: There are no data from human studies.

Elimination: There are no data from human studies.

Special Patient Populations: No special population studies were conducted.

6. Pharmaceutical Particulars

6.1. List of Excipients

Sodium di-hydrogen Phosphate 2H₂O
Disodium Hydrogen Phosphate 12H₂O
Disodium Edetate
Sodium Chloride
Methylhydroxypropylcellulose 4000
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special storage conditions

Keep out of reach and sight of children.
Store protected from Light.

6.5. Nature and specification of the container

10ml amber coloured neutral glass USP Type 1 bottle with Polystyrene droppers.

6.6. Instructions for Use and Handling

No special instructions for use and handling.

6.7. Manufacturing License Holder

Vivimed Labs Limited,
D-9, Industrial Area, Haridwar- 249401, Uttarakhand, India.

6.8. Marketed By

GlaxoSmithKline Consumer Private Limited,
Patiala Road, Nabha- 147201, Punjab, India

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