

**PRODUCT INFORMATION LEAFLET**

**1. Product Name**

**Brand Name:** Otrivin Paediatric Nasal Drops

**Generic Name:** Xylometazoline Hydrochloride Nasal Solution IP 0.05% w/v

**2. Qualitative & Quantitative Composition**

Contains:

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

In an aqueous isotonic solution using Purified water I.P... q.s.

Preservative:

Benzalkonium Chloride I.P. ... 0.01% w/v

**3. Dosage Form**

Nasal Drops

**4. Clinical Particulars**

**4.1. Uses/ Indications**

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

**4.2. Posology and method of administration**

Otrivin Paediatric is indicated in children aged 1 to 11 years old only under adult supervision. Otrivin 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)

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

Do not exceed 3 applications daily into each nostril. It is recommended to make the last application shortly before retiring to bed. Otrivin 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 are as below -***

1. Gently clear your child's nose.
2. Remove the bottle cap.
3. Before using, practice using the bottle as dropper to develop good dosage control.
4. Tilt your child's head slightly backward.
5. Apply the drops into each nostril without touching the nozzle and keep the head tilted back for a short time to allow the drops to spread throughout the nose.

6. If the drop completely misses the child's nose, administer the drop again.
7. If any part of the drop gets into the nose, do not administer the drop again.
8. Clean and dry the nozzle 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 Paediatric Nasal Drops should not be used if:

- If the child is below 1 year old.
- 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 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 in case of any such signs/symptoms.

Otrivin should be used with caution in below mentioned condition/s:

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

There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including xylometazoline. Symptoms reported included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. This product should be discontinued immediately and medical advice sought if signs/symptoms of PRES/RCVS develop.

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

#### **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 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**

*Not Applicable*

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

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

#### **4.8. Undesirable effects/side effects**

*Stop Otrivin and tell your doctor immediately in case patient experience these:*

- 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.

#### **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.

### **5. Pharmacological Properties and/or 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.

## **6. Pharmaceutical Particulars**

### **6.1. List of Excipients**

Sodium di-hydrogen Phosphate 2H<sub>2</sub>O  
Disodium Hydrogen Phosphate 12H<sub>2</sub>O  
Disodium Edetate  
Sodium Chloride  
Purified Water

### **6.2. Incompatibilities**

Not applicable

### **6.3. Shelf life**

36 months from date of manufacturing

### **6.4. Special storage conditions**

Keep out of reach and sight of children.  
Protect from Light and moisture.

### **6.5. Nature and specification of the container**

10 ml nasal solution in a white opaque plastic soft squeeze type bottle, plastic screw-on type cap.

### **6.6. Instructions for Use and Handling**

*For External Use Only*

### **6.7. Manufacturing License Holder**

Refer pack for details

### **6.8. Marketed By**

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

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