

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Otrivin Paediatric Oxy

Generic Name: Oxymetazoline Hydrochloride Nasal Solution/Nasal Drops I.P. 0.025% w/v.

2. Qualitative & Quantitative Composition

Contains:

Oxymetazoline Hydrochloride I.P 0.025% w/v

In a buffered aqueous solution

Preservative:

Benzalkonium Chloride IP 0.01 % w/v

3. Dosage Form

Nasal Solution/ 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

Dosage:

For Children 1-11 years of age.

Drops: 1 to 2 drops into each nostril, 2 to 3 times a day, as needed.

Minimum dosing interval: 8 hours.

To be administered on medical advice, under adult supervision only.

Be careful to avoid exposure to eyes. If any part of the drop gets into the nose, do not administer the drop again.

Maximum daily dose is three times daily into each nostril. It should not be used for more than 7 consecutive days. If symptoms persist, consult your doctor. Not recommended for use in infants and children below 1 year of age.

Instructions to administer Otrivin Paediatric Oxy Nasal Drops are as below -

Drops: Be careful to avoid exposure to eyes.

1. Gently clean your child's nose.
2. Tilt your child's head slightly back (as far as is comfortable).
3. Without touching the nose, carefully apply the drop(s) into each nostril. Keep the head tilted back for a short time to allow the drop(s) to spread throughout the nose.

4. If the drop completely misses the child's nose, administer the drop again.
5. If any part of the drop gets into the nose, do not repeat the dose.
6. Repeat for the other nostril.
7. Clean and dry the nozzle before replacing the cap after use.
8. To avoid possible spread of infection, the bottle should only be used by one person.

4.3. Contra-indications

Otrivin Paediatric Oxy Nasal drops should not be used if:

- infants & children below 1 year of age.
- Child is allergic to oxymetazoline 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); or surgery exposing the dura mater.
- 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

Check with your doctor before using Otrivin Paediatric Oxy if:

- Child suffer from high blood pressure, heart disease, overactive thyroid, prostate disease (prostatic hypertrophy), diabetes or phaeochromocytoma.
- Child is taking antidepressant medications. (please refer section 4.5)

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

0.025% w/v product strength is to be administered on medical advice, under adult supervision only. It should not be used for more than seven consecutive days. If symptoms do not improve, consult a doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

Keep out of the reach and sight of children.

Stop using this product and seek immediate medical attention if child experience:

Sudden severe headache.

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

4.5. Interaction with other medicaments and other forms of interaction

Consult physician before using Otrivin Paediatric Oxy nasal drops in case child is taking or has taken anti-depressant medications. These medicines are:

- monoamine oxidase inhibitors (MAOI): do NOT use this product if child is taking or have been taking MAOIs within the last 14 days;
- tri-cyclic and tetra-cyclic antidepressants.

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

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

4.7. Undesirable effects/side effects

The following convention has been utilised for the classification of the frequency of adverse reactions: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1000$, $< 1/100$), rare ($\geq 1/10000$, $< 1/1000$) or very rare ($< 1/10000$), not known (cannot be estimated from available data).

- *Common side effects:* nasal dryness and discomfort, sneezing.
- *Uncommon side effects:* dry mouth, stomatitis, dry throat and irritation.
- *Rare side effects:* Headache, insomnia, sedation, anxiety, irritability, nausea, hypertension, irregular heart rate, increased heart rate.
- *Very rare side effects:* Restlessness, Somnolence, Fatigue.

Stop taking Otrivin Paediatric Oxy and tell your doctor immediately if you experience any of the above, because Otrivin paediatric Oxy is not suitable in these circumstances.

4.8. Overdose

In case of accidental ingestion/ overdosage, contact your doctor or pharmacist immediately.

In case of over dosage, you may also contact the **National Poisons Information Centre of India. Details of the same are as below:**

Department of Pharmacology
All India Institute of Medical Sciences
New Delhi-110029
Toll Free No. - 1800 116 117
Tel No.- 26589391, 26593677
E-mail: npicaiims2010@gmail.com

5. Pharmacological Properties and/or mechanism of action

Mechanism of Action

Oxymetazoline is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors in the vessels of the nasal mucosa producing vasoconstriction

and decongestion.

6. Pharmaceutical Particulars

6.1. List of excipients

Disodium Hydrogen Phosphate anhydrous
Disodium Hydrogen Phosphate 12H₂O
Disodium EDTA
Monobasic Sodium Phosphate
Sodium Chloride
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 months from the date of manufacturing

6.4. Special storage conditions

Keep out of reach and sight of children.
Store in tightly closed container.

6.5. Nature and specification of the container

10 ml squeeze bottles.

6.6. Instructions for Use and Handling

For External Use Only

6.7. Manufacturing License Holder

Refer pack for details on manufacturing license holder.

6.8. Marketed By

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

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