

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Otrivin Oxy

Generic Name: Oxymetazoline Hydrochloride Nasal Solution I.P. 0.05% w/v.

2. Qualitative & Quantitative Composition

Contains:

Oxymetazoline Hydrochloride I.P..... 0.05% w/v

In a buffered aqueous solution

Preservative:

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

3. Dosage Form

Nasal Solution

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 Oxy is indicated in adults and in adolescents 12 years of age and above. Otrivin Oxy Nasal spray can be used as nasal spray or as nasal drops. The dose is as follows.

Dosage:

For adults and adolescents 12 years of age and above as;

Spray: 1 spray into each nostril, 1 to 2 times daily, as needed.

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

Do not exceed 2 applications of Otrivin Oxy daily into each nostril. It should not be used for more than 7 consecutive days. If symptoms persist, consult your doctor. Do not take a double dose to make up for a forgotten one.

Otrivin Oxy can be used both as a nasal spray and as nasal drops. Instructions to administer Otrivin Oxy are as below -

Spray: To produce a fine spray, the nebulizer should be held upright with the nozzle pointing upwards. Be careful not to spray in the eyes.

1. Clear your nose.
2. Remove the bottle cap.
3. Lean forward slightly and insert the nozzle into a nostril.

4. Squeeze the bottle hard in the center once and breathe in gently at the same time. Remove the nozzle before releasing the pressure on the bottle.
5. Take a deep breath. Repeat for the other nostril and replace the cap after use.
6. Clean and dry the nozzle before replacing back the cap right after use.
7. To avoid possible spread of infection, the spray should only be used by one person.
8. Do not take a double dose to make up for a forgotten one.

Drops: Otrivin Oxy nasal spray can also be used as a nasal drop.

1. Clear your nose.
2. Remove the bottle cap.
3. Tilt your head back as far as comfortable or, if lying on a bed, hang the head over the side.
4. Replace the cap right after use.
5. If the drop completely misses your nose, administer the drop again.
6. If any part of the drop gets into your 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 Oxy Nasal spray should not be used if:

- If the child is below 12 years of age.
- You are allergic to oxymetazoline or any other ingredients of this medicine
- You have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)
- You are suffering from narrow angle glaucoma (increased pressure in eyes)
- You have 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 Oxy if:

- You suffer from high blood pressure, heart disease, overactive thyroid, prostate disease (prostatic hypertrophy), diabetes or phaeochromocytoma.
- You are taking antidepressant medications.
- If you are pregnant or breast-feeding.

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.

Like other nasal decongestants, this product should not be used for more than 7 consecutive days. If symptoms do not improve or worsen, consult a doctor. Prolonged or excessive use may cause stuffiness in the nose to return or worsen.

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

Sudden severe headache.

Do not exceed the recommended dose.

For External Use Only.

4.5. Interaction with other medicaments and other forms of interaction

Consult physician before using Otrivin Oxy nasal spray in case you are taking or has taken anti-depressant medications. These medicines are:

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

4.6. Pregnancy and lactation

Pregnancy: Consult physician before using Otrivin Oxy.

Breastfeeding: Consult physician before using Otrivin Oxy.

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

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

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

4.9. Overdose

In case of accidental ingestion/ overdose, contact your doctor or pharmacist immediately. Do not take a double dose to make up for a forgotten dose.

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

5. Pharmacological Properties

5.1. Pharmacodynamic Properties & mechanism of action

Pharmacodynamics

ATC Code: R01A A05

Pharmacotherapeutic group: nasal decongestants for topical use, sympathomimetics, plain.

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. Pharmacotherapeutic group: decongestant medicine for local treatment, adrenergic.

The onset of effect of oxymetazoline is within 25 seconds and its effect lasts for up to 12 hours.

5.2. Pharmacokinetics

Absorption

Local use on the nasal mucosa leads to minimal systemic absorption. Nevertheless, systemic absorption of intranasal oxymetazoline 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

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

36 months

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

30 ml white opaque plastic soft squeeze type bottles.

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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