

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Otrivin Advance

Generic Name: Oxymetazoline HCl Metered Dose Nasal Spray

2. Qualitative & Quantitative Composition

Each spray contains: Oxymetazoline Hydrochloride I.P. - 50mcg

Composition: Oxymetazoline Hydrochloride I.P. – 0.05% w/w in a buffered Aqueous Solution

Benzalkonium Chloride Solution I.P. – 0.01% w/w (As Preservative)

3. Dosage Form

Nasal Spray

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 adults and adolescents 12 years of age and above: 1 spray into each nostril, 1 to 2 times daily as needed.

For nasal administration only. Do not exceed the stated dose. The lowest amount necessary to achieve benefit should be used for the shortest duration of treatment.

Minimum dosing interval: 8 hours. Maximum daily dose is twice daily into each nostril.

Do not exceed 2 applications of Otrivin Advance daily into each nostril. It should not be used for more than 10 consecutive days. If symptoms persist, consult your doctor.

Not recommended for use in children aged 6 to 11 years, except on the advice of a doctor. Do not use in children below 6 years of age.

Instructions to administer Otrivin Advance are as below -

Before first use, the pump should be sprayed several times into the air until an even spray is produced. If the spray has not been used for a few days or there is not an even spray, the initial process should be repeated.

1. Clear the nose.
2. Hold the bottle upright with thumb under base and nozzle between two fingers.
3. Lean forward slightly and insert the nozzle into a nostril.
4. Spray and breathe in gently through the nose at the same time.
5. Clean and dry the nozzle before replacing back the cap right after use.

To avoid possible spread of infection, the product should only be used by one person.

Be careful not to spray in the eyes.

If the full spray is not administered, the dose should not be repeated.

4.3. **Contra-indications**

Otrivin Advance Nasal spray should not be used if:

- If the child is below 6 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 Advance if:

- You have high blood pressure,
- You suffer from a heart disease,
- You have an overactive thyroid gland (hyperthyroidism),
- You suffer from diabetes,
- You have a rare tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma),
- You have an enlarged prostate gland (prostatic hypertrophy),
- You are taking certain medicines used for the treatment of depression. 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.
- 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 10 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. If you forget to use Otrivin Advance, do not take a double dose to make up for a forgotten one.

Keep out of the reach and sight of children.

4.5. **Interaction with other medicaments and other forms of interaction**

Consult physician before using Otrivin Advance 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 your physician before using Otrivin Advance.

Breastfeeding: Consult your physician before using Otrivin Advance.

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

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

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

4.9. Overdose

If you use too much medicine or in case of accidental ingestion, contact your doctor 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

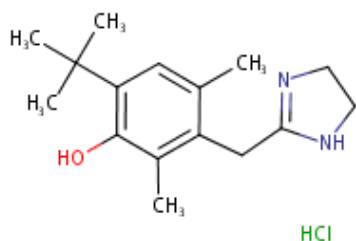
5. Pharmacological Properties and/or mechanism of action

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 Chemical structure



6.2. List of Excipients

Disodium Hydrogen Phosphate
Disodium EDTA
Monobasic Sodium Phosphate
Sodium Chloride
Hydrogenated Castor Oil
Menthol
Cineol
Sorbitol
Purified Water

6.3. Incompatibilities

Not applicable

6.4. Shelf life

24 months from the date of manufacturing

6.5. Special storage conditions

Keep out of reach and sight of children. Close the nozzle tightly with cap after every use.

6.6. Nature and specification of the container

10g Oxymetazoline HCl 0.05% w/w clear, colorless Nasal solution with characteristic mint odor in a white opaque plastic bottle snapped with metered dose pump.

Tamper evident Feature: Do not accept the pack if seal is broken or absent on the box/monocarton.

6.7. Instructions for Use and Handling

FOR EXTERNAL USE ONLY. FOR NASAL ADMINISTRATION ONLY

6.8. Manufacturing License Holder

Pontika Aerotech Limited,
Village Johron, PO Puruwala,
Nahan Road, Paonta Sahib, Dist.
Sirmour 173001 Himachal Pradesh, India

6.9. Marketed By

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

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