

PRODUCT INFORMATION LEAFLET

1. Product Name

Otrivin Breathe Clean

2. Qualitative & Quantitative Composition

Composition (% w/v)

Samudra Lavana (Sodium Chloride).....0.74%w/v

Excipients..... q.s.

Product contains inert Nitrogen which is used as Aerosol Propellant.

Contains Natural Glycerin.

“Ayurvedic Proprietary Medicine”

3. Dosage Form

Nasal Spray

4. Clinical Particulars

4.1. Indications/ Uses

- 1) Gently cleanse the nasal cavities when the nose is blocked, e.g. during a cold or in allergic conditions
- 2) Washes away the excess mucus or the allergen particles such as dust or pollen.
- 3) Soothe the irritated nasal passages.
- 4) Moisturize the nasal mucosa when dry or irritated in case of minor nasal irritations or due to low humidity (e.g. due to heated/air-conditioned rooms, high altitude, air travelling).
- 5) Thin and loosen nasal secretions and help their removal.
- 6) For daily nasal cleansing purpose.

4.2. Posology and method of administration

Read the instructions carefully before use.

Suitable for children above 2 years of age and adults. For children below 11 years, Otrivin Breathe Clean should be used under adult supervision.

Dosage: Spray briefly (2 to 3 seconds) in each nostril, 1 to 2 times a day. If necessary, the product can be used as often as needed.

For hygienic reasons and to avoid contamination, the nasal spray should only be used by one person.

Instructions for use:

1. Remove the protective cap of the spray. Blow the nose gently if necessary.
2. If the spray has not been used for a long time, prime the spray once into the air before use.
3. Using the opposite side hand delicately, insert the nozzle in the nostril aiming to the pupil of the eye on the same side and spray briefly (2 to 3 seconds) and allow the excess solution to trickle down. Repeat the same for other nostril.
4. Allow the product to act for a few seconds. Do not blow the nose during this time but wipe it if necessary. After each use and in case nozzle is blocked, clean the nozzle under hot running water, dry it properly with a clean tissue and put the protective cap back on.
5. Do not use chemical materials or dish washing liquid or disinfectant for cleaning it.

4.3. Contra-indications

Do not use the product in case of allergy to any of the ingredients.

4.4. Warnings and Precautions

- 1) Consult a doctor before use if you are using the product after nasal surgery or injury.
- 2) Due to its cleansing properties, Otrivin Breathe Clean should be used first when using another local nasal product (e.g. for cold or allergic rhinitis).
- 3) Keep out of reach and sight of Children.
- 4) Do not use a broken, expired or damaged product.

4.5. Interaction with other medicaments and other forms of interaction

NA

4.6. Pregnancy and lactation

Otrivin Breathe Clean may be used during pregnancy and breast-feeding, ask your doctor before using it.

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

NA

4.8. Undesirable effects/side effects

NA

4.9. Overdose

NA

5. Pharmacological Properties

5.1. Pharmacodynamic Properties & mechanism of action

Gently cleanse the nasal cavities when the nose is blocked, e.g. during a cold or in allergic conditions, by washing away the excess mucus or the allergen particles such as dust or pollen; Thin and loosen nasal secretions and help their removal.

5.2.Pharmacokinetics

NA

6. Pharmaceutical Particulars

6.1.List of Excipients

Glycerin
Monosodium Phosphate Dihydrate
Disodium Hydrogen Phosphate 12H₂O
Disodium Edetate
Purified Water

6.2.Incompatibilities

Not applicable

6.3.Shelf life

24 months

6.4.Special storage conditions

- 1) Store at an ambient room temperature and avoid excessive heat.
- 2) Do not expose to temperature exceeding 50°C. Do not refrigerate.
- 3) Store the spray in the original packaging box.
- 4) Keep away from sunlight. Do not puncture, break or burn even after use.
- 5) Pressurized container: May burst if heated.
- 6) Keep away from heat / sparks / open flames / hot surfaces. No smoking.
- 7) Do not microwave.

6.5.Nature and specification of the container

100 ml Can

6.6.Instructions for Use and Handling

Shake Well Before Use
For External Use only

6.7.Manufacturing License Holder

Pontika Aerotech Ltd.; Vill.Johran, P.O. Puruwala, Nahan Road, Paonta Sahib, Dist. Sirmour, 173001, H.P. India

6.8. Marketed By

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

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