

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Otrivin Breath Clean

Generic Name: Saline Nasal Solution

2. Qualitative & Quantitative Composition

Contains:

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

In an isotonic solution using Purified Water I.P. ... Q.S.

Product contains inert Nitrogen which is used as Aerosol Propellant.

Contains Natural Glycerin

3. Dosage Form

Nasal Solution

4. Clinical Particulars

4.1. Indications/Uses

Gently cleans the nasal cavities when nose is blocked during colds or in allergic conditions.

4.2. Posology and method of administration

Dosage:

Adults and Children > 2 years: 1 to 2 times a day per nostril and as often as needed.

For children below 11 years, Otrivin Breath Clean should be used under adult supervision.

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

4.3. Contra-indications

Do not use Otrivin Breath Clean if you are allergic to any of the ingredients (see ingredients list).

4.4. Warnings and Precautions

Consult a doctor before use if you are using the product after nasal surgery or injury.

Due to its cleansing properties, Otrivin Breath Clean nasal wash should be used first when using another local nasal product (e.g. for cold or allergic rhinitis).

4.5. Interaction with other medicaments and other forms of interaction

NA

4.6. Pregnancy and lactation

Otrivin Breath Clean nasal wash may be used during pregnancy and breast-feeding, ask your doctor or pharmacist before using it.

4.7. Undesirable effects/side effects

NA

4.8. 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. Glycerin acts as a moisturizer and helps soothe and moisturize the nose.

5.2. Pharmacokinetics

NA

6. Pharmaceutical Particulars

6.1. List of Excipients

Monobasic Sodium Phosphate Dihydrate
Disodium Hydrogen Phosphate 12H₂O
Disodium Edetate
Glycerin
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special storage conditions

Store below 30°C. Protect from heat.
Keep out of reach and sight of children.

Close the bottle tightly after use. Do not use the product after the expiry date shown on the packaging.

6.5. Nature and specification of the container

100 ml can, nasal solution and comes with an Aerosol Spray for greater coverage of the nasal passage.

**6.6. Instructions for Use and Handling
Spray:**

1. Clear your nose.
2. Remove the bottle cap.
3. Lean forward slightly and spray briefly into a nostril.
4. Blow the nose after usage.
5. Remove the nozzle from the nostril & then release the pressure on the bottle.
6. Repeat for the other nostril and replace the cap after use.

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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