

PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Otrivin Saline

Generic Name: Saline Nasal Solution

2. Qualitative & Quantitative Composition

Contains:

Sodium Chloride I.P..... 0.74 % w/v

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

Preservative:

Benzalkonium Chloride I.P.....0.01% % w/v

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:

Infants and toddlers up to 2 years: 1 spray/ nostril.

Adults and children > 2 years: 1-2 spray/ nostril as needed.

The usual frequency of use is 2 to 4 times a day per nostril.

Otrivin Saline is suitable for infants, children and adults. Seek medical advice before using Otrivin Saline in an infant less than 2 weeks old.

For children below 11 years, *Otrivin Saline* should be used under adult supervision.

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

4.3. Contra-indications

Do not use Otrivin Saline 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 Saline nasal spray should be used first when using another local nasal product (e.g. for cold or allergic rhinitis).

Otrivin Saline nasal spray contains benzalkonium chloride, a quaternary ammonium which could cause a local allergy in those sensitive to this substance.

4.5. Interaction with other medicaments and other forms of interaction

NA

4.6. Pregnancy and lactation

Otrivin Saline nasal spray 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.

5.2. Pharmacokinetics

NA

6. Pharmaceutical Particulars

6.1. List of Excipients

Benzalkonium Chloride
Monobasic Sodium Phosphate Dihydrate
Disodium Hydrogen Phosphate 12H₂O
Disodium Edetate.
Polyoxyl Hydrogenated Castor Oil
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

10 ml nasal solution in a white opaque plastic soft squeeze type bottle, plastic screw-on type cap.

6.6. Instructions for Use and Handling

Spray:

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.
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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