

## PRODUCT INFORMATION LEAFLET

### 1. Product Name

**Brand Name:** Otrivin Baby Saline

**Generic Name:** Saline Nasal Solution I.P.

### 2. Qualitative & Quantitative Composition

Contains:

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

In an isotonic aqueous buffered vehicle containing Aloe Vera.

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. Aloe Vera helps moisturize and soothe nasal cavities.

#### 4.2. Posology and method of administration

Otrivin Baby Saline is suitable for infants, children and adults.

Seek medical advice before using Otrivin Baby Saline in an infant less than 2 weeks old.

**Dosage:**

**Infants and toddlers up to 2 years:** 1 spray/ nostril or 1-2 drops per nostril

**Adults and children > 2 years:** 1-2 spray/ nostril or 2-3 drops per nostril.

The usual frequency of use is 2 to 4 times a day per nostril or as advised by the physician.

For children below 11 years, *Otrivin Baby 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 Baby 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 Baby Saline nasal spray should be used first when using another local nasal product (e.g. for cold or allergic rhinitis).

Otrivin Baby 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 Baby 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.

Aloe Vera helps moisturize and soothe nasal mucosa.

#### **5.2. Pharmacokinetics**

NA

### **6. Pharmaceutical Particulars**

#### **6.1. List of Excipients**

Benzalkonium Chloride solution  
Monosodium Phosphate Dihydrate  
Disodium Hydrogen Phosphate 12H<sub>2</sub>O  
Disodium Edetate.  
Polyoxyl Hydrogenated Castor Oil  
Plantalin Aloe Vera Powder  
Purified Water

#### **6.2. Incompatibilities**

Not applicable

**6.3. Shelf life**

36 months

**6.4. Special storage conditions**

Store in a cool place.

Keep out of reach and sight of children.

Close the bottle tightly after use.

**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**

**Instructions for Use**

**Spray:**

1. Clear 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.

**Drops:**

1. Clear nose.
2. Remove the bottle cap.
3. Tilt head backward.
4. Apply drops into nostril without the nozzle touching the nose, and remain still for a short time.
5. If the drop misses nose completely, repeat the dose.
6. Repeat for other nostril.

**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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