

## Instruction for use

**Manufacturer:**  
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 This product is a medical device Class I  
 Registered MS no: RO/I-020-224-01  
 Complying with MDD 93/42, annex I, annex VII

### Introduction

The individual saline mini-inhaler *Insalin* produces dry micro-particles of NaCl, thus being efficient as a complementary therapy in the treatment of different respiratory problems of the upper and lower respiratory tracts: bronchial asthma, bronchitis, sinusitis, rhinitis, respiratory allergies etc.

The process of obtaining the dry micro-particles of NaCl is accomplished through an absolutely innovative process based on forcing the air breathed in by its user through a layer of granular salt with a controlled structure. During the inhaling process the air passes through the granular layer and it engages it in an extremely visible "boiling" movement. The air under pressure erodes the micro crystals of salt generating dry salty micro-particles, the majority being under 5 microns.

*Insalin* is a device designed to be used anywhere, allowing its use before, after or during exposure to environments that tend to activate the respiratory problems: at school, in the gymnasium, at work, in crowded places. These are some of the situations when *Insalin* can be of a real use.

### 1 Mode of action

- The micronized sodium chloride (0,5-5µm) is easily inhaled through the upper and lower respiratory tracts;
- it dissolves in the outer layer of the mucus covering the respiratory epithelium;
- the mucus becomes more fluid, being easily mobilized;
- the inflammatory effect decreases and the degree of hydration of the mucus increases;
- the mucus becomes easier to eliminate at the level of the pharynxes and it is afterwards expectorated through cough.

### 2 General description

The inhaler *Insalin* is formed of a main body equipped in its lower part with slots permitting the air to enter and in its upper part with a mouthpiece that should be positioned between the lips when in use. Its central body is provided with two transparent curved windows allowing the visualization of the special salt granular layer positioned between two sieves. During the inhalation process the air passes through the granular layer and it engages it in an extremely visible "boiling" movement. The air under pressure erodes the micro crystals of salt generating dry salty micro-particles, the majority being under 5 microns.

The inhalers are packed together with the silica gel in a small plastic bag. Between uses the inhaler should be kept in the plastic bag and in a dry environment in order to preserve its optimal functional characteristics.

### 3 Preparation/ Operation

**Attention: Please follow the below mentioned instructions and obey them according to the explicative drawings:**

*Insalin* comes packed in a protective case formed of piece **A** and the removable lid **B**. Correctly closing the lid ensures a proper functioning of the device for an extended period of time.

- Insalin* is removed from its case by pressing down and towards the front of the caved part of the lid. The place that needs to be pressed is marked by 2 signs for the thumb
- The inhaler is easily stirred and the condition of the layer of salt should be verified through the transparent window. The salt granules should not be compressed.
- The upper extremity of the device is lightly positioned between the lips. Breathing in should be done through the mouth and breathing out through the nose, at a normal pace, effortlessly. Avoid a profound, forced breathing since it might cause an unpleasant, irritating cough.
- After utilization we recommend the wiping of the mouthpiece with a clean tissue, and then the inhaler should be kept in its case.
- The case closes by inserting the guides and the lid **B** inside the body **A**.
- The front part of the lid is pressed down until clearly inside the dedicated slot and the confirmation sound is heard.

**Symbols' description:**



The mucus becomes more fluid and it is easily mobilized by the vibrating cilia of the respiratory epithelial cells, in order to be eliminated at the pharyngeal level, by ameliorating the mucociliary clearance.
   
 By using *Insalin* inhaler significant therapeutic effects can be obtained in different diseases of the upper and lower respiratory tracts: asthma, rhinitis, bronchitis, sinusitis, respiratory allergies.
   
*Insalin* inhalers will provide their users with a permanent quantity of dry salt particles aerosols, thus allowing to achieve the therapeutic effects.

**5 Saline inhalations in the complementary respiratory therapy**
  
 When the air produced by this device is breathed in, the salt micro-particles enter the upper and lower respiratory tracts where they dissolve in the outer layer of the mucus covering the respiratory epithelium. The saline micro-particles physically act on the soft liquid layer covering the respiratory tracts, by modifying the superficial tension and viscosity.

**Attention:**
  
 The inhaler should be used by one person only. The extended mouth breathing can cause unwanted effects and we recommend you do not exceed 2 minutes per each use.

**4 Therapeutic recommendations**
  
**\* The device does not have contraindications.**
  
 The daily amount of salt breathed in at a normal use is under 0.05 grams.
   
 We recommend a daily use of this device, 10-15 inhalations, respectively 1-1,5 minutes/ 2-3 times per day. However, there is no limit regarding the daily number of uses.
   
 We recommend a proper body hydration by using liquids.

**Attention:**
  
*Insalin* inhaler offers a complementary treatment, which does not replace the current medical treatments. Do not stop and do not modify the current treatments!
   
 Please obey the advice of your doctor!

