

Subject: S3 Inhalation solution with herbal dry extracts and sodium hyaluronate, sterile solution without preservatives, in single-dose vials

Rev.03 - February 2025

Pages 1/2

INDICATIONS

The **Inhalation Solution S3** from the IN-NOSE line is a Medical Device for inhalation use consisting of a hypertonic, sterile, preservative-free and ready to use solution, based on herbal extracts of *Perilla Frutescens*, *Melissa Officinalis* and *Timo Serpyllum* in combination with hyaluronic acid, packed in a strip of 5 single-dose vials.

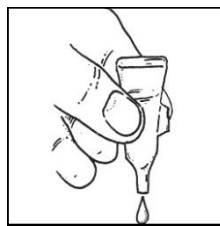
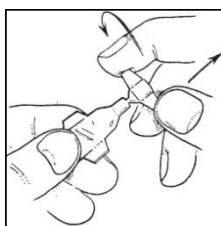
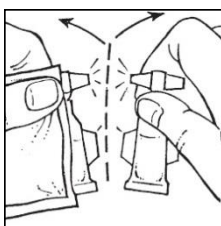
The **Inhalation Solution S3** is indicated to oppose and prevent the symptoms resulting from alterations in the trophism of the respiratory epithelium such as cough, rhinorrhea, pain typical of flu syndromes but also linked to external allergens. Behind these conditions there is a reduction in normal mucosal hydration and a consequent reduction in mucociliary clearance causing a vicious cycle that can lead to respiratory tract obstruction and to viral and bacterial infections.

Therefore, the nebulization of moisturizing substances, such as hyaluronic acid, is the correct therapeutic approach to restore the level of hydration, giving relief to the irritated mucosa. The hypertonia of the solution contributes to hydration allowing the fluidization and removal of the mucus. *Perilla* dry extract perform an antioxidant action and helps restore the physiological balance of respiratory mucosa.

The nebulization of the **Inhalation Solution S3** is optimal also for the cleaning of the nasal cavity and of the upper respiratory tract.

INSTRUCTION FOR USE

1. Blow the nose before starting the nebulization
2. Separate the single-dose vial from the strip
3. Shake gently the single-dose vial before the use
4. Twist and snap off the cap of the vial
5. Gently press the single-dose vial and put all the solution in the nebulizer ampoule (piston and ultrasonic nebulizer), without diluting it
6. After the nebulization, do not use any residue in the vial and/or in the nebulizer ampoule.



FREQUENCY OF USE

Nebulize a 3 mL vial, once or twice daily or according to the doctor's opinion. The product can be used with piston and ultrasonic nebulizer.

Nebulize a 5 mL vial, once or twice daily or according to the doctor's opinion. The product can be used with piston and ultrasonic nebulizer.

COMPOSITION

Sodium Chloride 2%, Hyaluronic Acid, dry extract of *Perilla Frutescens* (*polyphenols* $\geq 2,5\%$), dry extract of *Melissa Officinalis* (*rosmarinic acid* $\geq 12\%$), dry extract of *Thymus Serpyllum*, Sodium phosphate monobasic monohydrate, Sodium phosphate dibasic dihydrate, purified water.

Subject: S3 Inhalation solution with herbal dry extracts and sodium hyaluronate, sterile solution without preservatives, in single-dose vials

Rev.03 - February 2025

Pages 2/2

PACKAGING

The box is composed of 10 vials monodose of 3 mL, in strip of 5 vials.

The box is composed of 10 vials monodose of 5 mL, in strip of 5 vials.

WARNINGS

- ✓ The product is for inhalation use only, don't ingest or use otherwise than the indication of use
- ✓ Consult your doctor for pediatric use and for use during pregnancy and lactation
- ✓ Do not use under 2 years, because in this age the physiological characteristics of the respiratory tract lead to a limited drainage capacity of the bronchial mucus
- ✓ Clean your hands carefully before using the device
- ✓ Do not touch other surfaces with the tip of the vial, during the instillation of the solution in the cup
- ✓ Do not use the product in case of known incompatibility to even one single component of the formulation
- ✓ In case of adverse reactions during use, immediately suspend the treatment and consult a doctor or pharmacist
- ✓ Do not use the medical device mixed with inhaled drugs
- ✓ Keep out of reach of children
- ✓ Do not use the product after the expiration date indicated on the package
- ✓ Once the vial is open immediately drop out the content and do not reuse the remaining solution
- ✓ Keep unused vials inside the box
- ✓ In the event of any serious claims or incidents concerning the device, it should be reported the incident to the manufacturer and the competent authority of the Member State in which the user is established, to provide more information on the safety of this medical device.

VALIDITY

36 months with the package intact



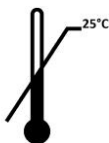
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Rev.03 - February 2025

Optional information:

