

Subject: Sterile inhalation solution S4 with thermal water Caesius of Bardolino and sodium hyaluronate medium molecular weight preservative free in a 3ml monodose vial

Rev. 03 - March 2026

Pages 1/2

INDICATIONS

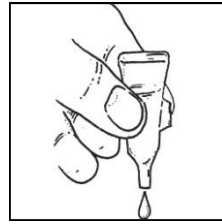
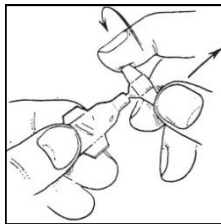
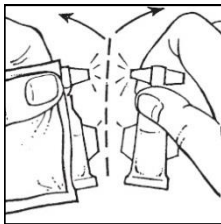
The **Inhalation Solution S4** is a Medical Device for inhalation consisting of a slightly hypertonic solution made with bicarbonate-calcic thermal spring water from the Caesius Baths in Bardolino (Vr) combined with Hyaluronic Acid.

It is a sterile, preservative-free solution designed to be nebulized and used with a nebulizer.

S4 Solution is indicated for the treatment of upper respiratory tract disorders linked to common colds, sinusitis, rhinitis and inflammation. Thanks to the combination of hyaluronic acid, thermal spring water and a mildly hypertonic formula, **Solution S4** guarantees a decongestant and hydrating action on the nasal mucosa, eliminating mucus and restoring the mucociliary clearance. Nebulized **S4 Solution** is also ideal for the physiological cleansing of the nasal cavity and upper respiratory tract.

INSTRUCTION FOR USE:

1. READY-TO-USE SOLUTION, DO NOT DILUTE;
2. BLOW YOUR NOSE BEFORE STARTING THE SESSION;
3. TEAR OFF THE SINGLE-DOSE VIAL FROM THE STRIP;
4. SHAKE THE SINGLE-DOSE VIAL GENTLY BEFORE USE;
5. TWIST AND SNAP OFF THE VIAL CAP;
6. EXERT MODERATE PRESSURE ON THE WALLS OF THE SINGLE-DOSE VIAL, DRAW OUT THE SOLUTION AND POUR IT INTO THE AMPOULE OF THE NEBULISER;
7. DO NOT USE ANY RESIDUAL CONTENTS IN THE VIAL AND/OR IN THE NEBULISER AMPOULE AFTER USE.



COMPOSITION: Caesius Thermal Spring Water from Bardolino, 0,1% Sodium Hyaluronate, 2% Sodium Chloride, Sodium phosphate monobasic monohydrate, Sodium phosphate dibasic dihydrate.

FREQUENCY OF USE:

Nebulize a 3ml vial once to twice a day or as advised by your doctor, without diluting it. The product can be used with all types of piston and ultrasonic nebulizers.

PACKAGING: The pack consists of 10 single-dose 3ml vials in strips of 5 vials.

WARNINGS:

- ✓ THE PRODUCT IS FOR INHALATION USE ONLY, DO NOT SWALLOW OR USE IN WAYS OTHER THAN THOSE INTENDED.
- ✓ CONSULT YOUR DOCTOR FOR USE IN PEDIATRIC AGE AND DURING PREGNANCY AND BREASTFEEDING.
- ✓ HANDS SHOULD BE THOROUGHLY WASHED BEFORE OPENING AND ADMINISTERING THE VIAL.
- ✓ WHEN POURING THE CONTENTS INTO THE AMPOULE, DO NOT TOUCH OTHER SURFACES WITH THE DISPENSING END OF THE VIAL.
- ✓ DO NOT USE THE PRODUCT IN THE EVENT OF KNOWN INCOMPATIBILITY WITH ANY COMPONENTS OF THE FORMULA.
- ✓ IN CASE OF DISORDERS SUCH AS BRONCHOSPASM, COUGHING OR ANY PERCEIVED IRRITATION DURING USE, DISCONTINUE TREATMENT IMMEDIATELY AND CONSULT YOUR DOCTOR OR PHARMACIST.

Subject:**Sterile inhalation solution S4 with thermal water Caesius of Bardolino and sodium hyaluronate medium molecular weight preservative free in a 3ml monodose vial**

Rev. 03 - March 2026

Pages 2/2

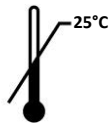
- ✓ DO NOT USE THE MEDICAL DEVICE MIXED WITH INHALED MEDICATIONS.
- ✓ KEEP OUT OF REACH OF CHILDREN.
- ✓ DO NOT USE THE PRODUCT AFTER THE EXPIRY DATE INDICATED ON THE PACK.
- ✓ ONCE THE VIAL HAS BEEN OPENED, USE THE CONTENTS IMMEDIATELY AND DO NOT REUSE ANY RESIDUAL CONTENTS.
- ✓ STORE UNUSED VIALS IN THE BOX.
- ✓ IN CASE OF ANY COMPLAINTS OR THE OCCURRENCE OF SERIOUS ACCIDENTS IN CONNECTION WITH THE DEVICE, THE MANUFACTURER AND COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER RESIDES MUST BE NOTIFIED.

VALIDITY: 36 months with the package intact.

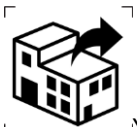
Enable Innovations S.r.l. - Via Claudio Tolomeo n°26; 41012 Carpi (MO), Italia



STERILE A



Rev.03 – March 2026

Optional pictogram

XXXXXX