



# Instructions for Use – please read carefully

## FUSION® Allergy Nasal Spray

Read this information carefully before you start using **FUSION® Allergy Nasal Spray**. **DO NOT THROW THIS LEAFLET AWAY!** It contains important information. If you have any questions about **FUSION® Allergy Nasal Spray** please ask your healthcare provider, pharmacist or Scope representative.

### 1. What is FUSION® Allergy Nasal Spray and what is it used for

**FUSION® Allergy Nasal Spray** is a nasal spray for the treatment and prevention of allergic rhinitis (hayfever) symptoms.

**FUSION® Allergy Nasal Spray** is a medical device which contains Ectoin®, a natural cell-protective molecule with inflammation-reducing and membrane-stabilizing properties.

**FUSION® Allergy Nasal Spray** is a slightly hypertonic solution and reduces the harmful influences of allergens and airborne particles. It supports the regeneration process of irritated nasal mucosa caused by allergens.

**FUSION® Allergy Nasal Spray** reduces allergen induced inflammations of the nasal mucosa. Alleviates allergic symptoms like running nose, itching nose, and nasal congestion.

**FUSION® Allergy Nasal Spray** is free of preservatives.

**FUSION® Allergy Nasal Spray** is suitable for sensitive noses and has no habituation effect. The Medical device is as effective as medicinal Azelastine (based on a calculated TNSS (total nasal symptom score) rated by physicians within a clinical study).

### 2. Warnings and precautions

- **FUSION® Allergy Nasal Spray** should not be used in the case of hypersensitivity to Ectoin® or any of the other ingredients of the nasal spray.
- If allergic reactions occur, the use of **FUSION® Allergy Nasal Spray** must be discontinued immediately.
- Do not use if the device is damaged or punctured.
- To ensure safe hygiene, each nasal spray bottle should only be used by one person.
- Do not use for more than 3 months after opening.
- **FUSION® Allergy Nasal Spray** should be kept out of reach of children.
- Do not use for more than 30 days continuously.

### 3. What you need to know before using FUSION® Allergy Nasal Spray

There are no data available regarding interactions between **FUSION® Allergy Nasal Spray** and other topical nasal treatments.

### 4. How to use FUSION® Allergy Nasal Spray

Always use **FUSION® Allergy Nasal Spray** according to these instructions for use.

If not otherwise prescribed by your healthcare provider, please apply 1-2 sprays in each nostril several times a day.

Children < 2 years must not administer more than 10 applications (of 2 sprays per nostril) per day.

There is no dosage restriction for persons ≥ 2 years.

Before using **FUSION® Allergy Nasal Spray** for the first time or if spray function is impaired, take off the cap and pump the bottle 2-3 times in upright position to release the air from the pump. Do not cut the tip.

1. Gently blow your nose to clean your nostrils.
2. Remove the cap from the bottle.
3. Hold the bottle with your index and middle finger on either side of the finger rests and your thumb underneath the bottle. Bend your head slightly forward and close one nostril by gently pressing against the side of your nose with your finger.
4. Insert the tip of the spray into your nostril. While pressing down the pump quickly and firmly, breath-in gently through the nose.
5. Insert the tip into your other nostril.
6. Repeat steps described above for the other nostril.
7. Wipe the exposed tip of the bottle with a clean lint-free cloth.
8. Replace cap on the bottle.





## 5. Possible side effects of FUSION® Allergy Nasal Spray

FUSION® Allergy Nasal Spray is well tolerated. Up to now, no regularly occurring or persisting side effects are known.

Please inform your healthcare provider, pharmacist, or Scope representative if you notice side effects that are associated with the use of FUSION® Allergy Nasal Spray.

If conditions persist or worsen, contact your healthcare provider or pharmacist.

## 6. How to store FUSION® Allergy Nasal Spray

The expiry date of FUSION® Allergy Nasal Spray is printed on the box and on the bottle.

FUSION® Allergy Nasal Spray must not be used after the expiry date has passed.

FUSION® Allergy Nasal Spray should be stored between 2 °C – 25 °C.

## 7. Additional information

If FUSION® Allergy Nasal Spray is applied within its intended use, there is no evidence for a particular risk during pregnancy or breast-feeding.

FUSION® Allergy Nasal Spray is suitable for children.

Children 10 years of age and younger and patients unable to use FUSION® Allergy Nasal Spray on their own should be assisted during the application of FUSION® Allergy Nasal Spray.

## 8. Content of FUSION® Allergy Nasal

20 mL solution

One spray contains 0.14 mL solution

**Ingredients:** Ectoin®, Sea Salt, and water

## 9. Legal Manufacturer



bitop AG  
Stockumer Str. 28,  
58453 Witten, Germany



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## 10. Date of information:

October 2023



CE mark



Lot number



Temperature  
limitation



Legal manufacturer



Use by date  
(Expiry date)



Please do not use damaged  
or punctured packaging



Please consider the  
instructions for use



Medical Device

