Instructions for Use – please read carefully FUSION® Allergy Eye Spray

Read this information carefully before you start using FUSION® Allergy Eye Spray. DO NOT THROW THIS LEAFLET AWAY!

It contains important information. If you have any questions about **FUSION® Allergy Eye Spray** please ask your healthcare provider, pharmacist, or Scope.

What is FUSION® Allergy Eye Spray and what is it used for?

FUSION® Allergy Eye Spray is a Medical Device which contains Ectoin®, a natural cell-protective molecule with inflammation-reducing and membrane-stabilising properties.

FUSION® Allergy Eye Spray is an eye spray for treatment and care of dry, irritated and inflamed eyes and eye- surrounding skin. It stabilizes and strengthens the tear film, alleviates dehydration and supports the regeneration process of irritated and sensitive conjunctiva. FUSION® Allergy Eye Spray moisturizes dry eyes and prevents further dehydration especially when used regularly. Symptoms of dry or allergic eyes such as burning, dryness, itching, redness, or foreign body sensation of the eyes can effectively be alleviated. Furthermore, symptoms of allergen induced inflammations are reduced.

Moreover, FUSION® Allergy Eye Spray reduces redness, scaling, and itching of the skin around the eyes. It soothes and nourishes the dry, irritated and inflamed eye area and reduces the feeling of tension. Furthermore, FUSION® Allergy Eye Spray calms irritated and tired eyes caused by air conditioning, wind, air pollution or swimming pool water. It refreshes and hydrates stressed skin and tired eyes ("office eye syndrome").

The eye spray is easy to handle, suitable for long-term use, sensitive eyes and all ages.

FUSION® Allergy Eye Spray is preserative free. The effects of FUSION® Allergy Eye Spray are clinically proven and based on 100% natural ingredients.

Warnings and precautions

- FUSION® Allergy Eye Spray should not be used after eye/ocular surgery, eye trauma, or any type of damaged cornea (the clear layer at the front of the eye).
- FUSION® Allergy Eye Spray should not be used in the case of hypersensitivity to Ectoin® or any of the other ingredients of the eye spray.
- Do not spray FUSION® Allergy Eye Spray into the open eye or touch the eye surface with the spray head.
- If allergic reactions occur, the use of FUSION® Allergy Eye Spray must be discontinued immediately.
- Do not use for more than 3 months after opening.
- FUSION® Allergy Eye Spray should be kept out of reach of children.
- Please do not use damaged or punctured products.

What you need to know before using FUSION® Allergy Eye Spray

FUSION* Allergy Eye Spray can be used together with contact lenses. FUSION* Allergy Eye Spray can be applied before make-up application or after make-up removal, If used after make-up has been applied, it is recommended to test the product with the make-up upon first use in order to ensure that no smudding will occur.

There are no data available regarding interactions between **FUSION® Allergy Eye Spray** and eye drops or topical eye ointments.

Therefore the usage with other ophthalmological treatments is not recommended.

How to use FUSION® Allergy Eye Spray

Always use **FUSION® Allergy Eye Spray** according to these instructions for use. Consult your healthcare provider or pharmacist before use if you are not sure.

If not otherwise prescribed by your healthcare provider, spray 1-2 times on the closed eyelids, several times a day. Children under 2 years shall not exceed a total amount of 4 applications (1-2 sprays per eye) a day. There is no dosage restriction for persons aged 2 years and over. If necessary, FUSION* Allergy Eye Spray can be used multiple times per hour.

- Remove the protective cap of the bottle and avoid any touching of the exposed tip.
- Before using FUSION® Allergy Eye Spray for the first time, pump several times to release the air from the pump.
- 3. Hold the bottle in front of your eye with a distance of approx. 10 cm.
- Keep the eye closed and spray on the eye lids.
- Slowly open your eye and blink a few times to transport the solution to your eye surface.
- 6. Repeat the procedure on the other eye.
- Carefully replace the protective cap after each usage of FUSION® Allergy Eye Spray.

Possible side effects of FUSION® Allergy Eye Spray

FUSION® Allergy Eye Spray is well tolerated. Up to now, no regularly occurring or persisting side effects are known. Please inform your healthcare provider, pharmacist, or Scope if you notice side effects that are associated with the use of FUSION® Allergy Eye Spray. If conditions persist or worsen, contact your healthcare provider or pharmacist.

How to store FUSION® Allergy Eye Spray

FUSION® Allergy Eye Spray should be stored between 2 °C – 25 °C. The expiry date of FUSION® Allergy Eye Spray is printed on the box and on the bottle. The product must not be used after the expiry date has passed.

Additional Information

Not all minor constituents of **FUSION® Allergy Eye Spray** have been extensively investigated for safety during pregnancy

and while breast-feeding. In the absence of sufficient data, the use of FUSION® Allergy Eye Spray during pregnancy and while breast-feeding is not recommended.

The eye spray allows an easy application for Children and elderly people and persons that feel uncomfortable using regular eye drops. Children 10 years of age and younger and patients unable to use FUSION® Allergy Eye Spray on their own should be assisted during the application of FUSION® Allergy Eye Spray.

Content of FUSION® Allergy Eye Spray

10 mL solution

Ingredients

Ectoin®, Soy Lecithin, Physiological Buffer System, Vitamin A, Vitamin E, Water

Manufacturer



bitop AG Stockumer Str. 28, 58453 Witten, Germany





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Date of information: October 2023



Use by date (Expiry date)



Please do not use damaged or punctured products



€ 019

STERILE

Legal Manufacturer

Α

Product is sterile by aseptic filtration

CE mark with notified body number



Please consider the instructions for use





LOT Number Medical Device

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FAS-101PL-2 PIL