

Instructions for Use – please read attentively

FUSION® Allergy Day & Night Eye Gel

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

1. What is FUSION® Allergy Day & Night Eye Gel and what is it used for

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

FUSION® Allergy Day & Night Eye Gel is a viscous isotonic solution and can be used for treatment and prevention of dry, irritated and inflamed eyes.

FUSION® Allergy Day & Night Eye Gel reduces burning, itching, foreign body sensation and allergen induced inflammations of the conjunctiva. It alleviates allergic symptoms, like red, itchy and watery eyes.

FUSION® Allergy Day & Night Eye Gel protects against the harmful influences of allergens and supports the regeneration process of irritated and sensitive conjunctiva such as wound healing after ocular surgeries or injuries of the eyes.

Based on pre-clinical data, **FUSION® Allergy Day & Night Eye Gel** provides an intensive and longer moisturisation of dry and irritated eyes, due to its prolonged retention time, compared with the eye drops.

FUSION® Allergy Day & Night Eye Gel stabilises the lipid layer of the tear film, reduces further dehydration and protects ocular cells from hyperosmolarity.

FUSION® Allergy Day & Night Eye Gel is suitable for all ages, wearers of contact lenses, for sensitive eyes and as preventive treatment.

FUSION® Allergy Day & Night Eye Gel is free of preservatives and phosphates. The effect is based on 100 % natural ingredients.

FUSION® Allergy Day & Night Eye Gel calms and soothes irritated and tired eyes.

FUSION® Allergy Day & Night Eye Gel is suitable for day-time and night-time use.

2. Warnings and precautions

- **FUSION® Allergy Day & Night Eye Gel** should not be used in the case of hypersensitivity to Ectoin® or any of the other ingredients of the eye drops.
- If allergic reactions due to the product occur, the use of **FUSION® Allergy Day & Night Eye Gel** must be discontinued immediately.
- Please do not use damaged or punctured products.
- To ensure safe hygiene, each eye drop bottle should only be used by one person.
- Do not use for more than 3 months after opening.
- **FUSION® Allergy Day & Night Eye Gel** should be kept out of reach of children.
- Please note that after the application of **FUSION® Allergy Day & Night Eye Gel** your vision may be impaired temporarily. If this is the case, do not drive vehicles or operate machines. Therefore, it is recommended to wait until normal visual acuity has returned.

3. What you need to know before using FUSION® Allergy Day & Night Eye Gel

There are no data available regarding interactions between **FUSION® Allergy Day & Night Eye Gel** and other eye drops or topical eye ointments, therefore the usage with other ophthalmological treatments is not recommended.

4. How to use FUSION® Allergy Day & Night Eye Gel

Always use **FUSION® Allergy Day & Night Eye Gel** 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, please apply 1-2 drops per eye, several times a day or during night. Children < 2 years should not exceed a total amount of 7 applications (1-2 drops per eye) a day. There is no dosage restriction for persons > 2 years. If necessary, **FUSION® Allergy Day & Night Eye Gel** can be used multiple times per hour.

1. It is recommended to wash your hands before using **FUSION® Allergy Day & Night Eye Gel**.
2. Before using **FUSION® Allergy Day & Night Eye Gel** for the first time, tear off the protective seal from the bottle.
3. Remove the protective cap of the bottle and avoid any touching of the exposed tip.
4. Bend your head slightly backwards.
5. Hold the bottle upside down in one hand between your thumb and forefinger or index finger. Please hold the bottle as vertical as possible.
6. Carefully open your eye by using your thumb and forefinger of the other hand or gently pull down your lower eye lid to form a pouch or pocket and look up.

7. Put the tip of the bottle close to your lower eye lid, but do not let it touch your eye.
8. Release one drop into the pouch or pocket formed between your eye and eye lid by gently squeezing the bottle.
9. Close your eye slowly to disperse the solution throughout the eye as good as possible.
10. Repeat the procedure on the other eye.
11. Carefully replace the protective cap after each usage of **FUSION® Allergy Day & Night Eye Gel**.

5. Possible side effects of FUSION® Allergy Day & Night Eye Gel

FUSION® Allergy Day & Night Eye Gel is well tolerated. Up to now, no regularly occurring or persisting side effects are known.

In isolated cases, **FUSION® Allergy Day & Night Eye Gel** may provoke short term eye irritation, ocular hyperaemia or conjunctivitis.

Please inform your healthcare provider, pharmacist, or Scope representative if you notice side effects that are associated with the use of **FUSION® Allergy Day & Night Eye Gel**.

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

6. How to store FUSION® Allergy Day & Night Eye Gel

The expiry date of **FUSION® Allergy Day & Night Eye Gel** is printed on the box and on the bottle.

FUSION® Allergy Day & Night Eye Gel must not be used after the expiry date has passed.

FUSION® Allergy Day & Night Eye Gel should be stored between 2 °C – 25 °C.

7. Additional information

If **FUSION® Allergy Day & Night Eye Gel** is applied within its intended use, there is no evidence for a particular risk during pregnancy or breast-feeding.

It is allowed to use **FUSION® Allergy Day & Night Eye Gel** after ocular surgeries or other ocular injuries to support wound healing.

The product is suitable for children. Nevertheless, children 10 years of age and younger and patients who may have difficulty using **FUSION® Allergy Day & Night Eye Gel** on their own should be assisted during the application of **FUSION® Allergy Day & Night Eye Gel**.


8. Content of FUSION® Allergy Day & Night Eye Gel and other information

10 mL solution

Ingredients

Ectoin®, Hydroxyethyl Cellulose, Sodium Chloride, Water, and Citrate Buffer

9. Legal Manufacturer

 bitop AG
Stockumer Str. 28,
58453 Witten,
Germany

 0197

SCOPE

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10. Date of information


October 2023


 0197 CE mark with
Notified Body number


 Legal Manufacturer


 Please consider the
instructions for use

 Lot number

 Use by date (Expiry date)

 Product is sterile by
aseptic filtration

 Please do not use damaged
or punctured products

 25°C
2°C Temperature limitation

 Medical Device