

OCUflash[®]

eye drops, solution

This product is a medical device. Please read this user guide before use. Keep this written information. You may need to read it again.

Product description

OCUflash eye drops, solution is an isotonic irrigation solution with additive of eyebright (*Euphrasia rostkoviana*) extract. The eye solution is filled in a multi-dose bottle sealed with a screw cap, marked with a label. The bottle is packed in a paper box together with instructions for use. 1 ml solution contains 30 drops.

Ocular irrigation

OCUflash eye drops, solution is the eye solution for flushing irritating particles or chemicals from the eye. Without a doctor's advice, it can be used for a simple short-term rinse, then for dripping into the eyes or eyelids compresses.

Disinfectant effect

Eyebright (*Euphrasia rostkoviana*) extract has anti-inflammatory, disinfectant and astringent properties in the eye. These characteristics of eyebright have long been used to soothe the eyes, as a prevention and supportive treatment of non-infectious inflammation of the eyelashes and conjunctiva. The product is suitable for use when removing cosmetic products from the eye area (eyelids, eyelashes).

The solution contains:

Sodium chloride 7 mg in 1 ml, benzalkonium chloride, disodium edetate, potassium chloride, magnesium chloride hexahydrate, polysorbate 80, eyebright (*Euphrasia rostkoviana*) tincture, borax, sodium hydroxide, purified water.

Excipients of known effect: a preservative – benzalkonium chloride 0.04 mg in 1 ml (0.004%), eyebright (*Euphrasia rostkoviana*) tincture 2.0 mg in 1 ml (0.2%).

Intended purpose

OCUflash eye drop, solution is intended to flush irritating particles, chemicals and foreign bodies from the eye, to flush the eye in case ocular surface injuries, and to drip into the eye when exposed to environmental factors (e.g. pollution, computer use, air conditioning) as prevention and complementary symptomatic treatment of non-infectious inflammation of the eyelids, conjunctiva and chronic conjunctiva infections.

Indications

Specific indications for OCUflash eye drops, solution include:

1. eyewash after tonometry and gonioscopy
2. eyewash after wearing hard contact lenses
3. eyewash, removal of foreign bodies, dust and chlorinated water
4. washing out residues of fluorescein solutions
5. washing out mucous and purulent secretions
6. as a first aid after mild burns of the conjunctiva and eyes with acids and bases (lime, mortar), ocular surface injuries
7. as a supportive remedy in some, mainly non-infectious conjunctivitis, chronic conjunctivitis.

Patient population and Intended users

OCUflash eye drops, solution can be used by adults, adolescents and children.

Limitations

There are no limitations concerning sex, age and/or weight of users. Considering the safety of the product, it can also be administered to newborns, infants, pregnant women and nursing mothers.

Dosage

Eyewash

When flushing any foreign bodies from the eye, apply the solution until the foreign substance or foreign bodies are removed, or until the discomfort disappears.

Non-infectious conjunctivitis

Drip 1–2 drops into the lower conjunctival sac 1–4 times a day.

Instruction before application

Once opened, OCUflash eye drops, solution is ready to be instilled into the eye. The patient unscrews the protective cap, tilts his/her head slightly, turns the bottle upside down and, squeezing it, drops the prescribed number of drops into the lower conjunctival sac. Amount of solution applied depends on the application. In inflammations of eyelid, the solution can also be used for compresses.

Contraindications

OCUflash eye drops, solution must not be used in the case of hypersensitivity to any of its ingredients.



Warnings

- Tell your doctor or pharmacist if you are allergic to any of the listed substances or preservatives. If you notice any side effects, contact your doctor.
- Do not use this device if you notice that the safety ring of the screw cap is broken or package is damaged before the first opening the bottle.
- Do not use this product after the expiry date, even if the bottle is still sealed. The expiry date is stated on the label or box next to the hourglass icon and refers to the last day of the month. Once the bottle has been opened, the product can only be used for a period of 28 days.
- Keep out of the sight and reach of children.

- The product cannot be used after the expiration date stated on the package, not even if the bottle is still sealed.
- When applying the product, the dropper should not touch the eye nor eyelid. After the application, the cap must be screwed on tightly to prevent possible contamination.



Cautions

Contact lens wearers

This preparation contains preservative substance benzalkonium chloride. Soft contact lenses may react with benzalkonium chloride and may change the colour of the contact lenses. Remove contact lenses from your eyes before using this product and after application wait 15 minutes before putting the contact lenses back in.

Other eye preparations used at the same time

If other eye drops or eye ointments are used at the same time with this product, wait for at least five minutes between the application of each product. Eye ointments should be applied last.

Shortly after instilling the product into the eye, blurred vision may occur temporarily. Therefore, do not drive motor vehicles or perform other activities that require increased attention until your ability to see returns to normal.

If the discomfort for which the product was applied does not improve and persists, or even worsens, see your eye ophthalmologist.

To reduce the risk of cross contamination and infection transmission, the content of one bottle should only be used by one person.

Undesirable side effects

OCUflash eye drops, solution is very well tolerated. Rarely, the following side effects may occur:

- Allergic reaction that may manifest as mild rash, exfoliative dermatitis or erythema multiforme
- Epithelial alterations, eye damage
- Hyperaemia
- Lacrimation
- Local irritation (burning, itching, stinging, mild discomfort)

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (neziaduceucinky@unimedpharma.sk) and the competent authority via the national reporting system of the Member State in which the user is established.

Interactions are not yet known.

Clinical benefit

OCUflash eye drops, solution helps prevent irritation, ocular damage, inflammation, or infection of the eye by flushing the eye surface of residual particulates such as foreign bodies, dust, fluorescein solution or mucous and suppurative secrets, that could otherwise damage the eye and/or cause inflammation or infection and exacerbation of the underlying condition. OCUflash may also be used as complementary symptomatic treatment of non-infectious inflammation of eye lids, conjunctiva and chronic conjunctiva infections.

Instructions for storage and disposal of the product

Store at room temperature 10 - 25°C. Store in the original package in order to protect from light and moisture.

Unused product return to the pharmacy.

Dispose of the clean packaging material responsibly in accordance with local guidelines in the appropriate separate waste container.

Contents of the pack:

Polyethylene (LDPE) bottle with LDPE dropper, white polypropylene (PP) screw cap with safety ring. The plastic bottle is packed into cardboard box.

Packaging size: 1 x 10 ml, 2 x 10 ml

Manufacturer:



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Email: unimedpharma@unimedpharma.sk

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Meaning of pictograms on the packaging

	Manufacturer		Batch code
	Date of Manufacture		Use-by date
	Temperature limit		Read the instructions for use
	Medical device		Do not use if package is damaged and consult instructions for use
	Sterilized using aseptic processing techniques		Keep dry
	Keep away from sunlight		Caution
	Drops per ml		Unique device identifier

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