

OCUhyl C®

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

OCUhyl C eye drops, solution is a preservative free ophthalmic solution containing sodium hyaluronate and marigold extract as main components. The eye solution is filled in a multi-dose bottle sealed with a special Novelia cap. The bottle is marked with a label, packed in a paper box together with instructions for use. 1 ml solution contains 30 drops.

Ocular moisturizing, hydrating and calming effect

Hyaluronic acid a substance naturally occurring in the eye and other parts of the body, thus eye drops provide an effective relief and long-lasting comfort from dry and burning sensation or eye tiredness. Marigold extract has protection, anti-inflammatory, and regeneration effect on the eye epithelium.

The solution contains:

Main constituent: Sodium hyaluronate 1.2 mg per 1 ml

Excipients: marigold extract, sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate, sodium acetate trihydrate, sodium citrate, water purified.

Excipients of known effect: Marigold (*Calendula officinalis*) extract 1.0 mg in 1 ml (0.1 %).

Contact lens wearers:

OCUhyl C does not contain preservatives, so it is ideal product for contact lens wearers and for people with sensitive eyes.

Intended purpose

OCUhyl C eye drops, solution is intended for an eye hydration, to create a temporary protective film on the eye cornea within insufficient tear formation, to improve tear film stability and quality thus moisturizing and protecting the eye surface. In conditions associated with dry eye symptoms.

Indications

OCUhyl C eye drops, solution is intended for user with mild, medium and severe dry eye disease of various etiologies:

- keratoconjunctivitis sicca,
- sjörgen syndrome,
- meibomian blepharitis,
- dry eye due to ageing/hormone changes such as perimenopause,
- postoperative dry eye,
- foreign body in the eye, fatigue and burning
- dry eye symptoms due to environmental and other factors such as pollution, computer use, air conditioning use, contact lens use, medication use

Patient population and Intended users

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

Limitations

Children younger than 2 years.

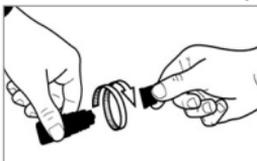
Dosage

Usually, 1 drop is applied to the eye 1 to 3 times a day, it can also be applied more often.

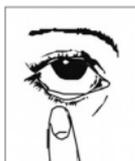
Instruction before application

Once opened, OCUhyl C eye drops, solution is ready to be instilled into the eye.

1. Wash your hands and sit or stand comfortably.
2. Unscrew the bottle cap.



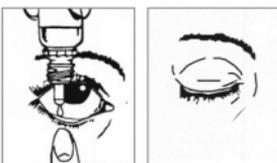
3. Hold the bottle downwards between the thumb and the other fingers.
4. Before the first application it is recommended to drop off the first drop out of the eye by gently squeezing the bottle, because in strong and irregular squeezing of the bottle the solution can be ejected in a larger volume.
5. Use your finger to gently pull down the lower eyelid of your affected eye.



6. Place the tip of the dropper close to your eye but so that it does not touch the eye or the adjacent regions of the eye.
7. Squeeze the bottle gently so that only 1 drop goes into your eye. Then release the lower eyelid and slowly close the eye so that OCUhyl C distributes evenly along the surface of the eye.

For the next drop, let suck back the air into the plastic bottle to return to its original state, and then continue to apply to the eye as recommended.

Please note that there might be a few seconds delay between squeezing and the drop coming out. The bottle must not be squeezed too hard.



8. If necessary, repeat the procedure for the second eye.



9. After use, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure sterility of the eye drops and easier delivery of the next drop in a subsequent application.

10. Immediately after application tightly close the bottle cap.

Contraindications

OCUhyl C eye drops, solution must not be used in the case of hypersensitivity (allergies) to any of its ingredients. Children younger than 2 years.



Warnings

- Tell your doctor or pharmacist if you are allergic to any of the listed substances. 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 damage 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 3 months.
- Keep out of the sight and reach of children.
- 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

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.

Driving and using machines

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 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

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

- Allergic reaction that may manifest as redness, itching, and swelling of the eyes
- Local irritation (itching, foreign body sensation or slight burning)
- Eye pain
- Conjunctival hyperaemia
- Temporary blurred vision

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

OCUhyl C eye drops, solution administered to the eye helps relieve relieve the symptoms of dryness and ocular discomfort and improve ocular surface health and healing.

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 Novelia dropper, threaded polyethylene cap furnished with safety ring, etiquette. The plastic bottle is packed into cardboard box.

Packaging size: 1 x 10 ml.

Manufacturer:



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Oriešková 11, 821 05 Bratislava,
Slovak Republic
Email: unimedpharma@unimedpharma.sk
www.unimedpharma.eu

Meaning of pictograms on the packaging

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|--|--|--|---|
| | 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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