

UNitears[®] preservative free

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

UNitears preservative free, eye drops, solution is a preservative free ophthalmic solution containing hypromellose and dexpanthenol 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 of the solution contains 20 drops.

Ocular moisturizing and hydrating

UNitears preservative free, eye drops, solution forms a temporary protective film on the cornea and conjunctiva, reducing tear evaporation and thus preventing further damage to the ocular surface from lack of tear fluid. The moisturising and protective effect of the product serves as a substitute for a lack of tear production.

Ocular surface regeneration

Dexpanthenol used as an additive helps in faster regeneration of cells on the surface of the cornea and conjunctiva. Thus, the product is also intended for epithelisation of the cornea and conjunctiva after eye injury or surgery.

The solution contains:

Main constituent: Hypromellose 5 mg in 1 ml.

Excipients: dexpanthenol, sodium chloride, disodium edetate, purified water.

Excipients of known effect: dexpanthenol 10 mg in 1 ml (1%).

Contact lens wearers:

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

Intended purpose

UNitears preservative free eye drops, solution is intended to create a temporary protective film on the eye cornea within insufficient tear formation thus moisturizing and protecting the eye surface in conditions associated with dry eye symptoms and in patients with small corneal erosions.

Indications

UNitears preservative free, eye drops, solution is intended for user with:

- dry eyes of various aetiologies (keratoconjunctivitis sicca, Sjogren's syndrome, computer vision syndrome, contact lens wearers with mild and moderate forms of dry eye, after ocular surgery and/or ocular injury);
- small corneal erosions of various aetiologies (after dropping small particles or after ocular surgery);
- uncomfortable feeling in the eyes (e.g. burning, itching, foreign body sensation) due to irritation caused by wind, dust, cigarette smoke, polluted air, contact lenses, etc.

Patient population and intended users

UNitears preservative free eye drops, solution can be used by adults, adolescents and children.

Limitations

- children younger than 1 year
- pregnant or breastfeeding women

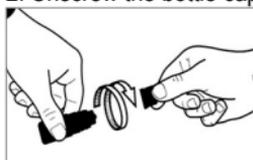
Dosage

The recommended dose is 1–2 drops drop into the conjunctival sac 2–6 times per day.

Instruction before application

Once opened, UNitears preservative free, eye drops, solution is ready to be instilled into the eye.

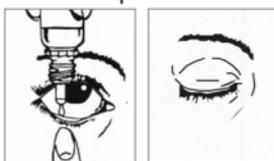
1. Wash your hands and sit or stand comfortably.
2. Unscrew the bottle cap.



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 1-2 drops go into your eye, or more drops in case of necessary rinsing. Then release the lower eyelid and slowly close the eye so that UNitears preservative free, eye drops, solution 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

UNItears preservative free eye drops, solution is contraindicated in

- patients with hypersensitivity to any components of the medical device.
- acute phase of corrosion of the eye until complete removal of corrosive substances from the conjunctival sac and removal of dead tissue
- children younger than 1 year



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 damaged before the first opening of 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

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

- Allergic reaction that may manifest as symptoms of local irritation,
- Local irritation (burning, itching, stinging, mild discomfort)
- Hyperaemia,
- Stickiness of eyelids,
- 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

UNItears preservative free eye drops, solution helps to relieve the symptoms of dryness, irritation, burning and ocular discomfort and improve the ocular surface diseases and support 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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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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