

# Potassium-U 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

Potassium-U preservative free eye drops solution is an isotonic irrigation solution including potassium iodide as an additive. 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.

### The solution contains:

Main constituent: Sodium chloride 2 mg per 1 ml

Excipients: potassium iodide, sodium thiosulfate, disodium edetate, sodium hydroxide, water purified.

Excipients of known effect: potassium iodide 20 mg in 1 ml (2%).

### Intended purpose

Potassium-U preservative free eye drops, solution is intended to be dropped into eye or to flush the eye of irritating particles to reduce inflammation, discomfort or risk of infection for prevention and supportive treatment of resorption processes for various eye conditions (e.g. exudates, hemorrhage, degenerative changes in corpus vitreum, cataracts of various etiologies) and supportive treatment of dry eye.

### Indications

Potassium-U preservative free eye drops, solution is intended for user with:

- Ocular irrigation to remove of irritating particulates, from environmental factors (e.g., pollution, computer use, air conditioning and contact lens use) or ocular injuries to reduce of eye inflammation, discomfort or risk of infection.
- Prevention and supportive treatment of resorption processes for various eye conditions (exudates, hemorrhage, corpus vitreum and cataracts of various etiologies) and dry eye supportive therapy.

### Patient population and intended users

Potassium-U preservative free eye drops, solution can be used by adults, adolescents and children.

### Limitations

- children younger than 12 year
- pregnant or breastfeeding women
- patients with defect function of thyroid gland

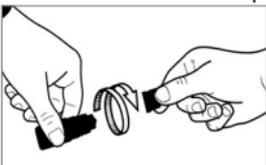
### Dosage

The recommended dose is 1–2 drops drop into the conjunctival sac 2–4 times per day or more drops (maximum 8 drops in a row) in case of necessary rinsing.

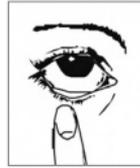
### Instruction before application

Once opened, Potassium-U 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.



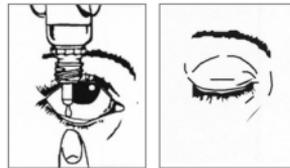
3. Hold the bottle downwards between the thumb and the other fingers.
4. Before the first application it is recommended to drop off the first drop out of the eye by gently squeezing the bottle, because in strong and irregular squeezing of the bottle the solution can be ejected in a larger volume.
5. 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 Potassium-U preservative free, eye drops, solutions 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

Potassium-U preservative free eye drops, solutions should not be used in case of hypersensitivity to any of its components, chronic pyodermy of the face skin, haemorrhagic diatheses, pregnancy and lactation, patients with defect function of thyroid gland and children younger than 12 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

#### Contact lens wearers

Although this preparation does not contain preservative substance it is recommended to 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.

#### 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

The following possible side effects may occur with using this medical device:

- Allergic reaction that may manifest as redness, itching, and swelling of the eyes.

- Local irritation (burning, increased tear secretion, foreign body sensation)
- Conjunctiva irritation,
- Eyelid edema,
- Lachrymal gland edema,
- Skin erythema, acne, dermatitis, purpura,

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

Potassium-U preservative free, eye drops, solutions may help to prevent ocular damage, inflammation and/or infection. Help relieve the symptoms of hemorrhage, blurred vision, dryness and irritation.

### 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:



UNIMED PHARMA spol. s.r.o.,  
Oriešková 11, 821 05 Bratislava,  
Slovak Republic  
Email: unimedpharma@unimedpharma.sk  
www.unimedpharma.eu

## 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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