

SENSIVIT[®]

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

SENSIVIT eye drops, solution is a special eye (sterile, isotonic, buffered) solution with A and E vitamins. 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 moisturizing, hydrating and lubrication effect

SENSIVIT eye drops, solution is a preparation with the moisturising and soothing effect. The solution stabilises all three tear layers on the eye surface (tear film). It contains carmellose sodium which, due to its properties, creates a temporary protective film on the surface of cornea and conjunctiva, moisturises the eye surface, and supports the aqueous component of tears, Vitamin A strengthens the inner (mucous) tear film component and together with vitamin E it improves nutrition of cornea and conjunctiva. Substances contained in the preparation strengthen also the outer (lipid) component of the tear film.

The solution contains:

Main constituent: Carmellose sodium 3 mg/ml,

Excipients: polysorbate 80, hydroxypropyl betadex, alpha-tocopheryl acetate, sodium chloride, hydroxystearoyl macrogol-glycerol, vitamin A, borax, disodium edetate dihydrate, benzalkonium chloride, water purified.

Excipients of known effect: a preservative – benzalkonium chloride 0.03 mg in 1 ml (0.003 %), retinol palmitate (vitamin A) 1000 I.U. in 1 ml, tocoferol acetate (vitamin E) 10 mg/ml (1 %).

Intended purpose

SENSIVIT eye drops, solution is intended for ocular use to create a temporary protective film on the eye cornea within insufficient tear formation to improve tear stability and quality and moisturize and protect the surface of eye.

Indications

SENSIVIT eye drops, solution is indicated for ocular use in patients with reduced tear production to moisturizing, protection and lubrication of eye surface.

- in conditions as keratoconjunctivitis sicca associated with feelings of dryness in the eye, irritation, redness, discharge, blurred vision, and easily fatigued eyes,
- corneal injury, corneal erosion and after eye surgery.

Patient population and Intended users

SENSIVIT eye drops, solution are intended to be used by adults, adolescents, and children.

Limitations:

- pregnant women and mothers in the breastfeeding period.
- children younger than 6 years

Dosage

Unless otherwise prescribed by the doctor, 1 drop is applied into the conjunctival sac 1-3 times a day. In children, the dosage is to be specified by a doctor.

Instruction before application

Once opened, SENSIVIT 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.

Contraindications

SENSIVIT eye drops, solution must not be used in the case of hypersensitivity to any of its ingredients. Children younger than 6 years.



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 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 28 days.
- 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

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.

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

SENSIVIT 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
- Temporary blurred vision
- Temporary mild burning
- Eye pain
- Eyelid margin crusting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (neziaduuceucinky@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

SENSIVIT eye drops, solution administered to the eye helps relieve ocular discomfort and key symptoms associated with reduced tear production and corneal defects (irritation, tearing, hyperaemia and photophobia) and improve corneal healing and support ocular surface regeneration.

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

Manufacturer:



UNIMED PHARMA spol. s r.o., Orišková 11, 821 05 Bratislava, Slovak Republic

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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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2265