

SeptoZINC

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

SeptoZINC eye drops, solution is a isotonic irrigation solution with additives of antiseptic and synergistic acting substances (zinc gluconate and benzalkonium chloride). 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

The eye drops facilitate the washout of irritating particulates from the ocular surface by creating a hydrodynamic flow that helps to mechanically dislodge and remove environmental irritants.

Disinfectant effect

The formulation includes zinc ions and benzalkonium chloride which exhibits antimicrobial effects. Antimicrobial effects of zinc ions depend on the reactive oxygen species generating mechanism while antiseptic properties of benzalkonium chloride are based on its surfactant properties and antibacterial and antiviral activities alone. These disinfectant effects are used in supportive treatment of eye infections (antibacterial and antiviral).

The solution contains:

Main constituent: Sodium chloride 7.5 mg in 1 ml,

Excipients: benzalkonium chloride, zinc gluconate, potassium chloride, magnesium chloride hexahydrate, calcium chloride dihydrate, sodium citrate, aqua purificata (water, purified).

Excipients of known effect: a preservative – benzalkonium chloride 0.2 mg in 1 ml (0.02%), zinc glukonate 1 mg in 1ml (0.1%).

Intended purpose

SeptoZINC eye drop, solution is intended to be used to flush the eye of irritating particulates and/or chemicals and to drip into the eye when exposed to environmental factors (e.g. pollution, computer use, air conditioning). To help prevent eye infections or as supportive treatment of conjunctiva and chronic conjunctiva infections.

Indications

SeptoZINC eye drops, solution is indicated for user with ocular injuries and/or mechanical impurities of cornea and/or conjunctiva and conjunctiva / chronic conjunctiva infections to

- Ocular irrigation to remove of irritating particulates and foreign bodies from environmental factors (e.g. drugs, 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 conjunctiva /chronical conjunctiva infection.

Patient population and Intended users

SeptoZINC eye drops, solution are intended for use in adults, adolescents, and children.

Limitations

Concerning sex, age and/or weight of users, there is limitation in children younger than 1 year.

Dosage

The recommended dose is 1 drop 3 times per day or more drops (maximum 6 drops in a row) in case of necessary rinsing.

Instruction before application

Once opened, SeptoZINC 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 purpose of the application.

Contraindications

SeptoZINC eye drops, solution are contraindicated in patient with hypersensitivity to any of ingredients of the medical device. Children younger than 1 year.



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 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 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.

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.

Caution is required in patients with dry eye syndrome and other ocular surface diseases and device use in these patients for longer than 14 days is not recommended.

Undesirable side effects

SeptoZINC 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
- 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

The intended clinical benefits of SeptoZINC eye drops, solution are:

- Prevention of irritation, ocular damage, infection caused by residual particulates remaining in the eye
- Complementary supportive treatment of conjunctiva / chronic conjunctival 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,

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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