

Package leaflet

Information for use, please, read carefully!

SENSILUX® UNIMED PHARMA®
(Tetryzolini hydrochloridum)

Drug form: eye drops, solution

Marketing authorization holder:

UNIMED PHARMA Ltd., Bratislava, Slovak Republic

Composition:

Active substance:

Tetryzolini hydrochloridum (tetryzoline hydrochloride) 0.5 mg in 1 mL of solution

Excipients:

Rutosidum trihydricum (ruthozide trihydrate), Benzalkonii chloridum (benzalconium chloride), Natrii chloridum (sodium chloride), Acidum boricum (boric acid), Natrii tetraboras (sodium tetraborate), Dinatrii edetas dihydricus (disodium edetane), Acidum hydrochloricum (hydrochloric acid), Aqua purificata (purified water).

Pharmacotherapeutic group: Ophthalmologics.

Characteristics: The SENSILUX® UNIMED PHARMA® product mitigates edema, conjunctiva congestion, feeling of burning, irritation, itching and aching; it contributes to relief in cases of smaller eye irritations of non-infectious origin. Tetryzoline initiates the eye conjunctiva vessels long-term contraction (vasoconstriction). Ruthozide is a substance of natural origin positively acting on the smallest vessels wall, increases their robustness and normalizes their permeability.

Indications: The SENSILUX® UNIMED PHARMA® product is used in cases of the eye conjunctiva edema, congestion and irritation initiated by wind, dust, light, smoke, chlorinated water, cosmetic products, or contact lenses. It is also used for elimination of allergic inflammatory symptoms, as corasthma and over-sensitiveness on bloom are.

Adults, youths and children of more than 7 years of age may use the product.

Contraindications: The SENSILUX® UNIMED PHARMA® must not be used in case of known over-sensitiveness on the product's individual components, during the eye infectious inflammations of viral or bacterial origin, in case of the conjunctiva and the cornea dry inflammation or in case of reduced tears production. Also the patients suffering from glaucoma with a narrow angle must not use it.

The SENSILUX® UNIMED PHARMA® eye drops, solution must not be applied to children up to two years of age.

For the eye solution instillation application to children of the age from 2 to 7 years and also for its application to mothers during pregnancy and lactation, there must be particularly special reasons and its usage is possible only based on a doctor



agreement.

Increased caution is required in case of the patients with serious affections of heart and vessels (heart rhythm defects, heart insufficiency, hypertension, etc.), with metabolic defect (diabetes, the thyroid increased activity), then in cases of the patients taking monoaminooxidase inhibitors (some drug products applied during depression treatment) and in case of the patients taking the drug products possibly increasing blood pressure.

If you suffer from some of the hereabove stated defects, inform your doctor about.

Unwanted effects: The product is very well tolerated. However, in case of over-application (very long time or very often), relative congestion, conjunctiva irritation, pricking, itching and burning in eye may occur. Rarely, corneas expansion, blurred vision or reaction due to over-sensitiveness may occur.

The overall unwanted effects occurrence (heart rhythm defects, high blood pressure, breathing problems, dizziness, headaches, insomnia etc.) is very rare and it is possible especially in case of incorrect and excessive usage.

Eventual occurrence of these unwanted effects or other unusual reactions report to your doctor.

Interactions: The SENSILUX® UNIMED PHARMA® product and other simultaneously used products effects may mutually affect. Therefore, your doctor should be informed about all medicines you actually use, or you had been recently using, or you plan to use, with or without prescription. If another doctor plans to prescribe to you a new medicine, inform him that you already use the SENSILUX® UNIMED PHARMA® eye drops, solution.

It is very important to make your doctor to know, if you already use the drug product for depression treatment or those potentially increasing blood pressure.

Also, if you use other eye medicines, consult suitability of their simultaneous using with your ophthalmologist. Generally, it is recommended to keep between application of other eye medicines and the SENSILUX® UNIMED PHARMA® product at least five minutes interval.

Dosage and drug application method:

Adults:

Usually, into the conjunctival sac 1-2 drops 2-3 times daily are dropped in.

Duration of application is individual, however, it is not recommended to exceed 14 days of uninterrupted application. The treatment is suitable to be finished after symptoms are gone. Irregularly, the product may be used without limitation.

Children older than 7 years:

If an ophthalmologist does not specify differently, usually 1 drop 1-2 times daily is applied into the conjunctival sac.

Attention: The product may rarely cause corneas expansion and blurred vision. In such case, ability to work in heights, to drive a motor vehicle and to operate machines is worsen.

Without consultation with a doctor, continual usage of the SENSILUX® UNIMED PHARMA® eye drops, solution for longer than 14 days is not recommended. If



affection symptoms do not improve up to two days, or they even get worse, using the product is necessary to be interrupted and consult with a doctor. The SENSILUX® UNIMED PHARMA® eye drops, solution is specified for moderate eye irritations treatment. So any eye irritations due to more serious reasons, as infectious illnesses, a foreign particle presence or cornea damage by chemicals are, require medicinal examination.

Simultaneously with the product application, wearing the soft contact lenses is restricted. The hard contact lenses should be removed before application and they may be slipped in soonest 20 minutes after the product application.

If dosing is in accordance with prescription, overdose is practically excepted. In case of small children there is increased a risk of overdose, especially if the SENSILUX® UNIMED PHARMA® eye drops, solution are incidentally swallowed. Signs of overdose are lethargy, somnolence or also irritation, irregular hearth frequency and blood pressure and body temperature changes. If some of these symptoms would occur, call a medicinal help immediately.

Warning: The product must not be used after the shelf life, stated on a package, expiration. The open container content should be used up to 28 days. After the medicine into the eye application, close a container immediately. The product must be stored out of the children hand.

Packaging: 1 × 10 mL

Storage: Do not store above 25°C. Do not refrigerate. Protect to light.

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