

# Visomitin®

**Dosage Form:** eye drops

**Structure:** In a 1 ml:

*Active ingredient:* Plastohinonildetsiltriphenylphosphonium bromide (PDTP) 0.155 mcg;

*Excipients:* benzalkonium chloride - 0.1 mg; hypromellose - 2 mg; sodium chloride - 9 mg; sodium dihydrogen phosphate dihydrate - 0.81 mg; sodium hydrogen phosphate dodecahydrate - 1.16 mg; sodium hydroxide 1M solution - up to pH 6–8; purified water - up to 1 ml

**Description:** Transparent or slightly opalescent, colorless or slightly colored liquid.

**Pharmacological classification:** Keratoprotective agent.

Antioxidant [Ophthalmic]

**ATC code:** S01XA

**Pharmacological action:**

keratoprotective

## **Pharmacodynamics**

PDTP is a derivative of plastoquinone, which is linked to the triphenylphosphine residue through the linker chain (C10). When used in low (nanomolar) concentrations, PDTP exhibits high antioxidant activity. It has a stimulating effect on the process of corneal epithelialization. It helps to increase the stability of the tear film.

One of the reasons for the development of the age-related cataracts is the damaging effect of UV radiation, which initiates the processes of photooxidation, leading to the denaturation of the main structural components of the lens - crystallins. The first protection of the eye tissues from UV radiation is tear fluid, which absorbs UV light in the range of 240-320 nm and neutralizes it due to the components of the tear fluid with the antioxidant

activity.

According to preclinical studies, the anti-cataract effect of Visomitin® is associated with an increase in the expression level of the main lens proteins,  $\alpha$ -crystallins.

According to a clinical study, an increase in the antioxidant activity of tears was recorded in patients with the age-related cataract who used Visomitin®.

## **Pharmacokinetics**

Preclinical animal studies have shown that PDTP in the blood is not detected when using Visomitin® eye drops in the form of instillations. After the oral administration of PDTP by healthy volunteers, T<sub>1/2</sub> in plasma is approximately 45 minutes.

## **Intended uses**

As the complex treatment of the following diseases:

- Symptoms of the dry eye / corneal conjunctival xerosis syndrome (poor tolerance to wind, air conditioning, smoke, foreign body sensation, smarting, burning, dry eyes, fluctuating visual acuity, lacrimation, eye redness in the area not covered by the eyelids);
- Symptoms of the initial stage of the age-related cataract (gradual obscuration and decreased visual acuity).

## **Contraindications**

Hypersensitivity to the drug components;

Children under 18 y.o. (no data from clinical studies).

## **Dosage and administration**

In the conjunctival sac.

Dry eye syndrome: 1-2 drops of the drug in the conjunctival sac 3 times a day. According to clinical studies, the therapeutic effect is achieved in the first 2–4 weeks of use. The therapeutic effect is persistent when the drug is applied for 6 weeks. If there is no effect during the first 2 weeks of treatment, a specialist examination is necessary.

The initial stage of age-related cataract: 1-2 drops of the drug in the conjunctival sac 3 times a day. The duration of treatment is 6 months. The "initial stage of age-related cataract" diagnosis should be established by a specialist.

If there is no improvement after the treatment or if symptoms aggravate, or new symptoms appear, the patient should consult a doctor.

The drug should be used only according to the indications, the method of use and at the doses indicated in the description.

### **Side effects**

*Visual organs:* often - short-term smarting and burning after instillation; infrequently - temporary eyesight dimout.

*Other:* often - allergic response (itching, redness and eyelid swelling and conjunctiva).

If any side effect indicated in the description appear or aggravate in a patient, or if a patient notice any other side effects not listed in the description, they should consult a doctor.

### **Overdose:**

When using Visomitin® in accordance with the instruction for use, an overdose is unlikely.

Symptoms: in case of excessive use, side effects may intensify.

Treatment: symptomatic therapy.

### **Interaction with other drugs**

No adverse interaction of Visomitin® with other drugs have been previously noted.

If necessary, it can be used simultaneously with other eye drops, the interval between instillations should be at least 15 minutes.

### **Pregnancy and lactation:**

There is no data on the safety of using Visomitin® during pregnancy.

Studies of the generative function and teratogenic effect in rats have not revealed any signs of impaired fertility or defects in fetal development because of PDTP.

It is unknown whether PDTP is excreted in breast milk. Appropriate studies in lactating women have not been conducted.

The use of Visomitin® during pregnancy is possible if the intended benefit to the mother outweighs the potential risk to the fetus.

If the patient is pregnant, or thinks that she might be pregnant, or is planning a pregnancy, she needs to consult a doctor.

### **Special Instructions:**

Contact lenses.

Visomitin® eye drops contain benzalkonium chloride as a preservative, and they are not recommended for use when wearing contact lenses. Before instilling eye drops, contact

lenses should be removed and put on again no earlier than 15 minutes after using the drug.

The bottle must be closed after each use.

Do not touch the eyes with the tip of the pipette while instilling.

The active ingredient of Visomitin® is very sensitive to light: between uses, the bottle should be stored in a dark place.

Patients using Visomitin® to relieve symptoms of the dry eye syndrome and as the supportive treatment of cataracts without prescription should consult a doctor in the following cases:

Use of the drug to relieve symptoms of the dry eye syndrome for 6 weeks and more;

- Presence of purulent discharge in the eyes;
- Redness of eye areas covered by the eyelids;
- Sharp (from one day to a month) visual deterioration;
- Appearance of new symptoms or change in previously observed symptoms related to the organs of vision.

Patients suffering from long-term recurring symptoms of the dry eye syndrome or progressive visual deterioration because of cataracts should be regularly examined by an ophthalmologist.

**Terms of release from pharmacy:** without prescription.

**Storage conditions:** store in a dry dark place at temperatures no higher than 2-8°C. Keep out of reach of children.

**Shelf life:** 2 years. Use the opened bottle within 1 month. Do not use beyond the expiration date printed on the package.

**Country of manufacture:** Russia