Visomitin®

Registration number:
LP-001355

Trade name:
Visomitin®

International nonproprietary name or group name:
None

Dosage form:
Eye drops

Composition per 1 ml:
Active ingredient: Plastoquinonyl decyl triphenylphosphonium bromide (PDTF) 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 1 M solution to pH 6.3 - 7.3, water for injection to 1 ml.

Description:
Clear or slightly opalescent colorless or slightly colored liquid.

Pharmacotherapeutic group:
Keratoprotective agent. Antioxidant agent.

ATC code:
S01XA

Pharmacological properties:

Pharmacodynamics:
Plastoquinonyl decyl triphenylphosphonium bromide (PDTF) is a derivative of plastoquinone, which is linked through a linker chain (C10) to a triphenylphosphine residue. PDTF shows high antioxidant activity at low (nanomolar) concentrations. It also has a stimulating effect on tear production and epithelialization processes, helping to increase tear film stability. One of the causes of age-related cataracts is the damaging effect of ultraviolet radiation, which initiates photooxidation processes leading to denaturation of the main structural component of the lens - crystallins.

The first protection of eye tissues from ultraviolet radiation is tear fluid, which absorbs ultraviolet light in the range of 240-320 nm and neutralizes it through the antioxidant activity components of tear fluid. According to preclinical studies, the anti-cataract action of Visomitin® is associated with increased expression levels of the main lens proteins β-crystallins, restoration of lens epithelium, and activation of energy processes in it.

According to clinical studies, patients with age-related cataracts who used Visomitin® showed increased antioxidant activity in tears.

Pharmacokinetics:
No pharmacokinetic studies have been conducted in humans. In preclinical animal studies, PDTF distribution in organs and tissues occurred within 48 hours after intravenous and intragastric administration. PDTF was found in highest concentrations in kidney, liver, and heart tissues within 1-2 hours after administration. PDTF is relatively quickly subjected to enzymatic breakdown and covalent binding to proteins.

Indications for use:
Dry eye syndrome. Initial stage of age-related cataracts.

Contraindications:
Hypersensitivity to product components, age under 18 years.

Use during pregnancy and breastfeeding:
Adequate controlled studies in pregnant and breastfeeding women have not been conducted. The drug is not recommended during pregnancy. If necessary to prescribe during lactation, breastfeeding should be discontinued for the duration of treatment.

Method of administration and dosage:

Dry eye syndrome: 1-2 drops of the drug in the conjunctival sac 3 times daily. Duration of treatment is determined by the physician depending on disease severity.

Initial stage of age-related cataracts: 1-2 drops of the drug in the conjunctival sac 3 times daily. Duration of treatment is 6 months. During therapy with the drug, ophthalmologist monitoring is necessary to assess disease progression and the need for continued conservative therapy.

Side effects:

Allergic reactions. Sensory organs: temporary burning and stinging sensation in the eyes after instillation may occur.

Overdose:

No data on overdose with topical application.

Drug interactions:

Can be used simultaneously with other eye drops if necessary. The interval between instillations should be at least 5 minutes.

Special instructions:

Effect on ability to drive vehicles and operate machinery:
If temporary blurred vision occurs after using the drug, it is not recommended to drive vehicles or engage in activities requiring increased concentration until vision is restored.

Presentation:

Eye drops with concentration 0.155 mcg/ml in polyethylene bottles of 5 ml with dropper stoppers and screw caps. Each bottle with usage instructions is placed in a cardboard box.

Storage conditions:

Store in a light-protected place at temperature 2-8°C. Once opened, store the bottle in a light-protected place at 2-8°C; use within 1 month.

Keep out of reach of children.

Shelf life:

2 years.

Do not use after the expiration date shown on the package. Use opened bottle within 1 month.

Dispensing conditions:

Prescription only

Manufacturer

Mitotech LLC, Russia.

These instructions translated from official manufacturer instructions in Russian by Extrapharma online pharmacy