

Patient Information Leaflet for Medical Device Gylan[®] Extra ophthalmic moisturizing solution according to TS 21.20.23-027-64260974-2020

Description and composition

Gylan[®] Extra ophthalmic moisturizing solution (hereinafter referred to as the solution, product) is a transparent colorless slightly viscous solution.

Ingredients per 1 mL: trehalose – 30.0 mg, sodium chloride – 6.0 mg, sodium hyaluronate – 1.8 mg, trometamol – 1.0 mg, hydrochloric acid – up to pH 6.0 – 7.8, water for injection – up to 1 mL.

Scope and administration

The field of application is ophthalmology.

Gylan[®] Extra is intended for eye care by intraconjunctival instillation.

Gylan[®] Extra ophthalmic moisturizing solution reproduces the action of natural tears, protects and moisturizes the ocular surfaces and lubricates them. This product has a long-term facilitatory action on dry eyes caused by various factors:

- Tear film disorders, which leads to tear hyposecretion and causes symptoms of discomfort;
- External impact (central heating, climatic installations, fluorescent lamps, chlorinated water, conditioned air, various natural phenomena such as wind, cold, dust, smoke, smog);
- Frequent prolonged work at a computer monitor;
- Use of vasoconstrictors or anti-inflammatory ophthalmic preparations;
- Changes in endocrine profile (menopause);
- Elderly age (75% of the population over 65 suffers from dry eye syndrome).

Properties and efficacy

Gylan[®] Extra is a sterile ophthalmic solution without preservatives that contains trehalose 30 mg/mL (3%) and sodium hyaluronate 1.8 mg/mL (0.18%). Trehalose has physical and chemical characteristics that provide protective, antioxidant and moisturizing properties. For these reasons, it is an important element in the anhydropic mechanism observed in certain microorganisms (a state of slow metabolism that allows them to survive under dehydration conditions). Trehalose has protective and stabilizing properties in relation to cell membranes, preventing protein denaturation and lipid degradation, and it also exhibits antioxidant functions. Trehalose is a naturally occurring substance found in many animals and plants that can survive in extremely dry conditions. Sodium hyaluronate is highly purified, produced by bacterial fermentation. Sodium hyaluronate is a physiological polysaccharide compound contained in both eye tissues and other tissues and fluids of the human body. A special physical and chemical property of sodium hyaluronate molecules is their pronounced ability to bind water molecules.

Thanks to the combination of trehalose and sodium hyaluronate, Gylan[®] Extra protects, moisturizes and lubricates the ocular surfaces for a long time and quickly gives a feeling of comfort.

The content of trehalose and sodium hyaluronate in Gylan[®] Extra gives a double moisturizing of the ocular surfaces.

When applying Gylan[®] Extra ophthalmic solution, a thin uniform film is formed on the epithelium of the cornea, protecting the eye from overdrying, irritation and development of inflammation of the eyeball anterior surface. The protective film action begins instantly, thus the eyes are protected for a long time from the sensation of dryness, sandpaper in the eyes, foreign body sensation, irritation, which often occur when working at a computer, with prolonged use of air conditioners or other office equipment, in cases of environmental degradation. The pre-corneal tear film formed after instillation is retained for a long period of time, is not washed away when blinking and does not cause a decrement in visual acuity.

Gylan[®] Extra effectively and quickly relieves symptoms of dry eye syndrome: eliminates the foreign body sensation, burning sensation, sandpaper in the eyes, helps to relieve fatigue during intensive visual load, eliminates discomfort, maintains a healthy eye condition.

When wearing contact lenses systematically, it is recommended to use Gylan[®] Extra ophthalmic solution, which promotes long-term moisturizing of the eye, as its action is identical to the natural lacrimal fluid. The solution has a viscosity index of 2.0 – 25.0 mPa.s. Gylan[®] Extra solution makes wearing hard or soft contact lenses more comfortable, while the solution does not settle on the lens surface.

Gylan[®] Extra ophthalmic solution does not contain preservatives, so there is no undesirable toxic effect on eye tissues, it is well tolerated even with prolonged use.

Thanks to a special drop dispenser the solution remains sterile during the entire shelf life after opening the bottle. Sterility of the solution after opening the bottle is due to the drop dispenser design – the presence of a special spring, which prevents the return of the solution to the bottle with the remaining solution after

instillation, thus eliminating the contact of the solution in the bottle with the solution that got into the external environment and the presence of sterilizing multilayer filter membrane in the air channel of the drop dispenser.

Indications and usage

- Moisturizing the anterior ocular surfaces (cornea and conjunctiva) in dry eye syndrome;
- Elimination of dry eye sensation, sandpaper in the eyes, burning sensation, lacrimation, redness, itching, ocular fatigue, "office" syndrome, as well as the sensation of a foreign body in the eye, eye strain feeling, after various eye disorders, especially after conjunctivitis and keratitis of various etiologies;
- Complex treatment of chronic blepharitis, causing the dry eye syndrome;
- Elimination of dry eye sensation in cases of systematic and prolonged use of medications;
- Complex treatment of dry eyes in cases of constant use of cosmetic products, as well as after faciaplasty;
- Moisturizing the anterior ocular surfaces after ophthalmic surgical operations, including after refractive interventions, as well as in case of minor corneal damage as part of complex therapy;
- Elimination of discomfort when wearing hard and soft contact lenses, as well as for the prevention of dry eye syndrome in contact lens vision correction;
- Prevention and complex treatment of corneconjunctival xerosis in case of deterioration of ecological situation and environmental pollution, and prolonged visual loads;
- Sjogren's syndrome.

Administration during pregnancy and breast-feeding period

There are no safety data on the use of Gylan[®] Extra solution during pregnancy and breast-feeding period.

Contraindications

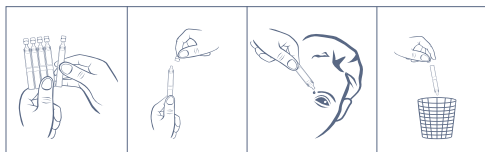
Increased sensation to any of the components included in the Gylan[®] Extra solution.

Administration and dosage

Gylan[®] Extra ophthalmic moisturizing solution is instilled 1-2 drops into the conjunctival sac as the circumstances require to 6 times a day.

Method of Gylan[®] Extra solution instillation

How to use a dropper tube (unidose)



1. Separate one dropper tube.
2. Open the dropper tube (making sure that the solution is in the lower part of the dropper tube, rotate and separate the valve).

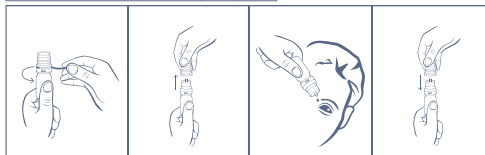
Before opening the dropper tube it is recommended to wash or treat hands with antiseptic.

3. Instill the required amount of solution into the eyes.
4. Avoid contact of the tip of the open dropper tube with ocular surfaces and hands.

4. Close the dropper tube with the valve.

An opened dropper tube can be stored no more than 6 hours, then the dropper tube should be discarded, even if there are still contents.

How to use a bottle with a drop dispenser



1. Remove the retaining ring before using the bottle for the first time.
2. Carefully remove the cap from the bottle. Without touching the dispenser, turn the bottle upside down with the dispenser secured between the thumb and index finger.
Before use, it is recommended to pump the dispenser until the first drop of solution appears by pressing several times with the index finger on top of the bottle.
3. Throw your head back, position the bottle dispenser over the eye and pull the lower eyelid downward with the index finger of one hand. Slightly press the bottle and instill the required amount of solution into the conjunctival sac. Avoid contact of the tip of the open bottle with ocular surfaces and hands.
4. After use, put the cap on the bottle.

After each instillation it is necessary to wait a few seconds without pressing on the bottle so that it fills again with the necessary amount of air. This is due to the special sterile air filtration system. Otherwise, it may be difficult to continue instillation.

After opening the bottle, the solution can be used for the entire shelf life.

If the bottle is visibly damaged, Gylan® Extra solution should not be used.

Precautions for use

Gylan® Extra solution should not be used with damaged or opened packaging.

Potential side effects when using a medical device

Possible allergic reactions.

A possible feeling of eyelids sticking together due to the solution viscosity.

Drug-to-drug interactions

In case of combined use with ophthalmic preparations it is recommended to observe a pause of at least 10 minutes between instillation of Gylan® Extra solution and application of eye drops.

Eye ointments should always be applied after instillation of Gylan® Extra solution.

Special warnings

Gylan® Extra does not belong to the products that can affect psychomotor state of a person.

It does not effect on ability to drive and use machines.

Presentation

0.4 mL of solution in a dropper tube (unidose) of polyethylene or 10 mL in a bottle of polyethylene, complete with a drop dispenser.

5 or 10 dropper tubes or 1 bottle in a foil or metallized film bag (for a bottle – if necessary).

1, 2, 4, 6 or 8 bags with 5 dropper tubes or 1, 2, 3 or 4 bags with 10 dropper tubes, or 1 bag with a bottle complete with a drop dispenser, together with a patient information leaflet in a cardboard pack.

It is allowed to enclose 1 bottle without a bag together with a patient information leaflet in a cardboard pack.

It is allowed to enclose 1 dropper tube (unidose) on a cardboard tray in a foil or metallized film bag as a consumer package without patient information leaflet. It is allowed to wrap the cardboard pack with polymer film.

Labeling

STERILE A

Sterilization using aseptic processing methods.



Do not use if the package is damaged.



Refer to the patient information leaflet.



Dropper tube (unidose)



Compatible with contact lenses



Without preservatives



For the eyes

Storage conditions

Store at +2°C to +25°C.

Do not freeze.

Keep out of reach of children.

Expiration date

In a bottle – 3 years. After opening the bottle, the solution can be used for the entire shelf life.

In a dropper tube in a bag – 3 years. After opening the bag – 1 year.

Do not use after expiration date!

Transportation conditions

By all types of covered vehicles in accordance with the haulage rules, operating on each type of vehicle, at +2°C to +25°C. Do not freeze. Keep away from heat. Protect from moisture.

Manufacturer/claims acceptance organization/marketing authorization holder

Grotex LLC, Russia
195279, St. Petersburg, Industrialnyi Avenue, 71, building 2, lit. A
Tel.: +7 812 385 47 87
Fax: +7 812 385 47 88
www.solopharm.com
www.gylan.ru

Specific and essential performance of medical device

Gylan® Extra ophthalmic moisturizing solution in dropper tubes (unidoses) or in a bottle with a drop dispenser is produced according to TS 21.20.23-027-64260974-2020 in compliance with international and national standards.

Dropper tubes (unidoses) with a nominal volume of 0,5 mL ± 8% are made of polyethylene granules of Purell, Bormed, Eltex® MED, HLD01S, PE MG013 R, SABIC® LDPE PCG06, BB120, complying with the current European Pharmacopoeia.

The full volume bottle of 13 ± 1 mL is made of low density polyethylene (LDPE) of Purell PE 1810 E, LDPE 15803-020, Purell PE 1840 H.

In terms of biological safety the solution meets the requirements of GOST ISO 10993 series of standards. The solution is biologically safe.

The solution is sterile. The solution is poured under aseptic conditions in accordance with GOST R ISO 13408-1.

Requirements for use and operation of medical device

The solution is intended for use in medical institutions and at home.

It is recommended to use the product individually. The solution in dropper tubes (unidoses) is intended for use within 6 hours after opening.

Performing procedures with this medical device at home does not require special training and special skills.

Warranty

This product has been designed, manufactured, tested and packaged in compliance with all relevant requirements.

The manufacturer guarantees the product quality until the expiry date, provided that the conditions of transportation, packaging integrity, storage and use are observed.

Disposal procedure

Dispose of the medicinal product (including unused solution) in accordance with SanPiN 2.1.3684-21 as class A waste (epidemiologically non-hazardous waste with composition close to solid municipal waste).