

Description and composition

Gylan[®] Dex Moisturizing Ophthalmic Solution (hereinafter – the solution, the product) is a colorless, slightly viscous solution.

Product version: Gylan[®] Dex.

Composition: Dexpanthenol 2% (16.0–24.0 mg/ml), Sorbitol (18.00–22.00 mg/ml), Disodium hydrogen phosphate dihydrate (7.48–9.14 mg/ml), Sodium dihydrogen phosphate dihydrate (2.83–3.45 mg/ml), Sodium hyaluronate 0.18% (1.8 ± 0.36 mg/ml), Water for injection (up to 1 ml).

Scope and administration

The field of application is ophthalmology.

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

Gylan[®] Dex 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[®] Dex is a sterile 0.18% aqueous sodium hyaluronate solution with 2% dexpanthenol, free of preservatives.

The active substance, highly purified sodium hyaluronate, is produced by bacterial fermentation. Sodium hyaluronate is a physiological polysaccharide compound found both in eye tissues and in other human tissues and fluids.

A specific physicochemical property of sodium hyaluronate molecules is their strong ability to bind water molecules. Its aqueous solution (GYLAN) has the necessary viscosity and strong adhesive properties, effectively moisturizing the eye surface.

The solution also contains provitamin B5 (dexpanthenol), which has high water-binding capacity, further moisturizing the eyes and enhancing the hydration effect of sodium hyaluronate. Dexpanthenol also has anti-inflammatory and wound-healing properties, supporting faster regeneration of the eyes after trauma and surgery.

When applied, Gylan[®] Dex forms a thin, even film on the corneal epithelium, protecting the eyes from dryness, irritation, and inflammation of the anterior eye surface. The protective film acts instantly and provides long-term protection from dryness, burning, foreign body sensation, and irritation caused by computer work, air conditioning, or environmental factors. The precorneal tear film formed after instillation remains stable for a long time, is not washed away by blinking, and does not impair visual acuity.

Adequate eye surface hydration with Gylan[®] Dex helps normalize physiological processes and accelerates healing after trauma and surgery.

Gylan[®] Dex effectively and rapidly relieves symptoms of dry eye syndrome of varying severity: eliminates foreign body sensation, burning, and stinging, reduces fatigue from intense visual strain, relieves discomfort, and helps maintain healthy eyes.

In cases of regular contact lens wear, Gylan[®] Dex is recommended as it provides long-lasting eye hydration, similar to natural tears. Viscosity: 3.5–15.0 mPa·s. It makes both soft and rigid contact lenses more comfortable to wear without depositing on their surfaces.

The solution contains no preservatives, thus avoiding toxic effects on eye tissues and being well tolerated even with prolonged use.

Thanks to the special dropper bottle, the solution remains sterile throughout its shelf life after opening. Sterility is ensured by the design

of the dropper: a spring mechanism prevents backflow into the bottle, and a sterilizing multilayer membrane filter in the air channel maintains sterility.

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 facioptasty;
- 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[®] Dex solution during pregnancy and breast-feeding period.

Contraindications

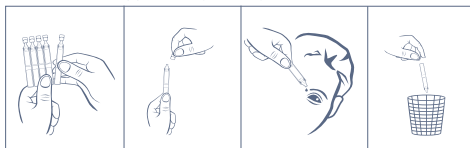
Increased sensation to any of the components included in the Gylan[®] Dex solution.

Administration and dosage

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

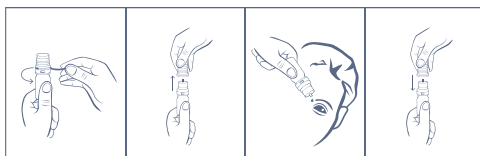
Method of Gylan[®] Dex solution instillation

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.
- 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® Dex solution should not be used.

Precautions for use

Gylan® Dex 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® Dex solution and application of eye drops.
Eye ointments should always be applied after instillation of Gylan® Dex solution.

Special warnings

Gylan® Dex 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



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

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Specific and essential performance of medical device

Gylan® Dex 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).