

## Package insert

### Gylan Comfort moisturizing ophthalmic solution

#### Description and composition

Gylan Comfort is an odorless, slightly viscous, colorless solution.

1 dropper tube (unidose) or vial of Gylan Comfort contains: sodium hyaluronate – 0,18 % ( $1,8 \pm 0,36$  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), water for injection (up to 0,4 ml or 10 ml).

#### Field of application

Ophthalmology. The solution is designed for eye care by instillation into the conjunctival sac.

The solution reproduces the action of natural tears, protects and moisturizes the surface of the eye and lubricates it. It provides a long-lasting relief in case of dry eyes caused by various factors:

- disturbance of the tear film, which leads to a decrease in the secretion of tears and causes symptoms of discomfort;
- the influence of the external environment (central heating, climatic installations, fluorescent lamps, chlorinated water, air conditioning, various natural phenomena - wind, cold, dust, smoke, smog);
- frequent prolonged work at the computer monitor;
- use of vasoconstrictive or anti-inflammatory ophthalmic drugs;
- changes in the hormonal background (menopause);
- elderly age (75 % of the population over 65 years old suffers from the «dry» eye syndrome).

#### Properties

Gylan Comfort is a sterile 0,18 % aqueous sodium hyaluronate solution, which does not contain preservatives.

Active substance is a highly purified sodium hyaluronate produced by the bacterial method fermentation. Sodium hyaluronate is a physiological polysaccharide compound which contained in the tissues of the eye, and other tissues and fluids of the human body.

A special physicochemical property of molecules of sodium hyaluronate is their pronounced ability to bind molecules of water.

Gylan has the necessary viscosity and high adhesive properties. After instillation of the solution, a thin uniform film is formed on the corneal epithelium, which protects eyes from drying out, irritation and growth of inflammation of the anterior surface of

the eyeball. The protective film acts almost immediately, that is why the eyes are permanently protected from dryness, cramps, foreign body sensations, irritations that often occur when working at a computer, with prolonged use of air conditioners or other office equipment, in cases of environmental degradation. It is recommended to use solution if you systematically wear contact lenses. The solution contributes to long-lasting eye moisturizing, its action is identical to an action of natural tear fluid.

Viscosity index of solution is 3,5 - 8,0 mPa.s.

The solution does not contain preservatives, and there is no undesirable toxic effect on the eye tissue.

#### Indications for use

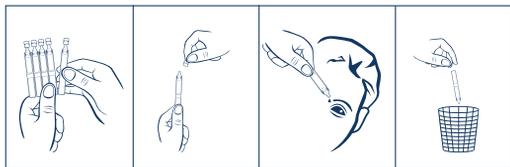
- syndrome of a «dry» eye of moderate severity;
- sensation of dry eyes, «sandy feeling» in the eyes, burning, lacrimation, redness, itching, fatigue, «computer vision» syndrome, as well as sensation of a foreign body in the eye, after various eye diseases, especially after conjunctivitis and keratitis of various etiologies;
- chronic blepharitis, which causes of the «dry» eye syndrome;
- «dryness» of the eye in cases of systematic and prolonged use of medicines (hormonal, anti-inflammatory drugs, antibiotics, etc.);
- «dryness» of the eye in cases of constant use of cosmetic, as well as after facial plastic surgery;
- moistening the anterior surface of the eye after ophthalmic surgical operations, including after refractive interventions (LASIK, PRK, etc.), as well as with minor damage to the cornea in the complex therapy;
- discomfort and dry eye syndrome during the rigid and soft contact lenses wear;
- corneal conjunctival xerosis in case of deterioration of the ecological situation and pollution of the environment (smog, smoke, dust, etc.), and prolonged visual loads;
- Sjogren's syndrome.

#### Recommended dosage

Instill 1-2 drops of solution in the conjunctival sac, up to 6 times daily, if necessary.

#### Method of instillation

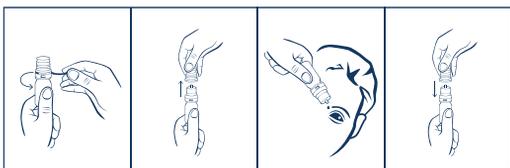
Use of a solution in a dropper tube (unidose)



1. Separate the dropper tube.
2. Open the dropper tube (make sure that solution is at the bottom of dropper tube, rotate and separate the valve).
3. Instill the solution into the eyes.

Amount of solution in a dropper tube is sufficient for one instillation of both eyes.

#### Use of the solution in a vial



1. Remove the protective plastic ring before first use of the vial.
2. Carefully remove the cap from the vial. Turn the vial dispenser down, without touching the dispenser, locking it between thumb and forefinger. Before use, it is recommended to pump the dispenser until the first drop of the solution appears by pressing the index finger on top of the bottle.
3. Tilt the head back, pull the lower eyelid down with an index finger of one hand. Lightly press the vial and drip the required amount of the solution into the conjunctival sac. Avoid contact of the tip of open vial with the surface of eye and hands.
4. Put the cap on the vial, after use.

#### Contraindications for use

Hypersensitivity to any components of the solution.

#### Precautions for use

Do not use the product if the packaging, dropper tube (unidose) or vial is damaged.

#### Possible adverse reactions

Rarely allergic reactions. Sometimes there is a feeling of gluing of the eyelids due to viscosity of solution.

#### Interactions

In case of combined use with ophthalmic drugs, it is recommended to wait at least 30 minutes between instillation of the solution and other medicine.

Eye ointments should always be applied after instillation of the solution.

#### Special precaution

If you are pregnant or breast-feeding, think you may be pregnant, ask your doctor or pharmacist for advice before taking.

The solution does not affect motor responses.

#### Requirements for the use

Solution is intended for use in medical institutions and home. The product is for individual use. Using at home does not require special training and special skills.

#### Release form

0,4 ml of solution in a polyethylene dropper tube (unidose) or 10 ml in vial, equipped with a dropper.  
5, 10, 20, 30 dropper tube (unidoses) or 1 vial with a dropper and package insert in the cardboard box.

#### Shelf life

3 years.  
Do not use after expiry date!

#### Manufacturer:

Grotex LLC, Russian Federation, 195279,  
Saint Petersburg, Industrialny av. 71, bld. 2, lit. A  
Tel.: + 7 812 385 47 87  
Fax: +7 812 385 47 88  
www.solopharm.com  
www.gylandrops.ru

#### Storage conditions

Store at temperature from +5 °C to +25 °C. Keep out of reach of children.  
Keep away from heat. Keep out of direct sunlight and source of open flame.

Sterilization using aseptic processing techniques.  
Do not use if package is damaged.  
See package insert for directions for use and important safety information.  
Do not resterilize.

