3 Simple Steps for Placement

1. **Pocket**
   Gently grasp the outer corner of the lower eyelid between your thumb and index finger and pull out to create a “pocket”.

2. **Place**
   Place LACRISERT® by gently brushing it on the inside of the “pocket”.

3. **Pull up and over**
   Pull the lower lid up and over the LACRISERT®, then release. Allow LACRISERT® to settle comfortably in the “pocket”.

**Application Tips**

- Add a drop or two of artificial tears after placement to expedite softening.
- Put contact lens in first, then place LACRISERT®.
- If using makeup, put makeup on first, then place LACRISERT®.
- LACRISERT® may be used at night or in the morning.

Lacrisert is soluble, and begins to soften. As Lacrisert dissolves throughout the day, it provides continuous lubrication and protection.

Please see Important Safety Information on back.
Incorrect Placement
LACRISERT® shouldn’t touch the white part of the eye or be visible on the rim of the lower lid.

Correct Placement
LACRISERT® should rest in the pink part under the lower eyelid.

When placed correctly, it should be completely out of sight and feel comfortable. LACRISERT® acts like a slow release artificial tear to help provide ongoing lubrication and protection.


Indications and Usage
LACRISERT® (hydroxypropyl cellulose ophthalmic insert) is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. LACRISERT® is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions. LACRISERT® is also indicated for patients with exposure keratitis, decreased corneal sensitivity, and recurrent corneal erosions.

Important Safety Information
- LACRISERT® (hydroxypropyl cellulose ophthalmic insert) is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose.
- Instructions for inserting and removing LACRISERT® should be carefully followed.
- If improperly placed, LACRISERT® may result in corneal abrasion. Because LACRISERT® may cause transient blurred vision, patients should be instructed to exercise caution when driving or operating machinery.
- The following adverse reactions have been reported, but were in most instances mild and temporary: transient blurring of vision, ocular discomfort or irritation, matting or stickiness of eyelashes, photophobia, hypersensitivity, eyelid edema, and hyperemia.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information, including Instructions for Use.

For more information on LACRISERT®, plus FREE samples and coupons, go to www.LACRISERT.com

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The molecular weight is typically 1 x 10^6.

Hydroxypropyl cellulose is an off-white, odorless, tasteless powder. It is soluble in water below 38°C, and in many polar organic solvents such as ethanol, propylene glycol, dioxygen, mannitol, isopropl alcohol (95%), dimethyl sulfoxide, and dimethyl formamide.

Each LACRISERT is 5 mg of hydroxypropyl cellulose. LACRISERT contains no preservatives or other ingredients. It is about 1.27 mm in diameter by about 3.5 mm long. LACRISERT is supplied in packages of 60 units, together with illustrated instructions and a special applicator for removing LACRISERT from the unit dose blister and inserting it into the eye. A spare applicator is included in each package.

CLINICAL PHARMACOLOGY

Pharmacodynamics

LACRISERT acts to stabilize and thicken the precorneal tear film and prolong the tear film breakup time which is usually accelerated in patients with dry eye states. LACRISERT also acts to lubricate and protect the eye.

LACRISERT usually reduces the signs and symptoms resulting from moderate to severe dry eye syndromes, such as conjunctival hyperemia, corneal and conjunctival staining with rose Bengal, exudation, itching, burning, foreign body sensation, smarting, photophobia, dryness and blurred or cloudy vision. Progressive visual deterioration which occurs in some patients may be retarded, halted, or sometimes reversed.

In a multicenter crossover study the 5 mg LACRISERT administered once a day during the waking hours was compared to artificial tears used four or more times daily. There was some patients may be retarded, halted, or sometimes reversed.

In a multicenter crossover study the 5 mg LACRISERT administered once a day during the waking hours was compared to artificial tears used four or more times daily. There was a decrease in foreign body sensation associated with dry eye syndrome in patients during treatment with LACRISERT as compared to artificial tears; these findings were statistically significantly different between the treatment groups. Improvement, as measured by amelioration of symptoms, by slit lamp examination and by rose Bengal staining of the cornea and conjunctiva, was greater in most patients with moderate to severe symptoms during treatment with LACRISERT.

In most patients treated with LACRISERT for over one year, improvement was observed as evidenced by amelioration of symptoms generally associated with keratoconjunctivitis sicca such as burning, tearing, foreign body sensation, itching, photophobia and blurred or cloudy vision. During studies in healthy volunteers, a thickened precorneal tear film was usually observed through the slit-lamp while LACRISERT was present in the conjunctival sac.

Pharmacokinetics and Metabolism

Hydroxypropyl cellulose is a physiologically inert substance. In a study of rats fed hydroxypropyl cellulose, unmodified cellulose at levels up to 5% of their diet, it was found that the two were biologically equivalent in that neither was metabolized.

Studies conducted in rats fed 5C-labeled hydroxypropyl cellulose demonstrated that when orally administered, hydroxypropyl cellulose is not absorbed from the gastrointestinal tract and is quantitatively excreted in the feces.

Dissolution studies in rabbits showed that hydroxypropyl cellulose inserts became softer within 1 hour after they were placed in the conjunctival sac. Most of the inserts dissolved completely in 14 to 18 hours; with a single exception, all had disappeared by 24 hours after insertion. Similar dissolution of the inserts was observed during prolonged administration (up to 54 weeks).

INDICATIONS AND USAGE

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LACRISERT is also indicated for patients with:

- Exposure keratitis
- Decreased corneal sensitivity
- Recurrent corneal erosions

CONTRAINDICATIONS

LACRISERT is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose.

WARNINGS

Instructions for inserting and removing LACRISERT should be carefully followed.