PRODUCT MONOGRAPH

STERILE OPHTHALMIC INSERT

LACRISERT®

(hydroxypropyl cellulose ocular system, USP)

5 mg

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Imported by:
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PRODUCT MONOGRAPH

STERILE OPHTHALMIC INSERT

LACRISERT®
(hydroxypropyl cellulose ocular system, USP)
5 mg

LACRISERT® (hydroxypropyl cellulose ocular system, USP) ophthalmic insert is a rod-shaped, water soluble, ophthalmic preparation made of hydroxypropyl cellulose, 5 mg. LACRISERT® contains no preservatives or other ingredients. It is about 1.27 mm in diameter by about 3.5 mm long.

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, tearing, itching, burning, foreign body sensation, smarting, photophobia, dryness and blurred vision. Progressive visual deterioration which occurs in some patients may be retarded, halted, or sometimes reversed.

In four crossover studies the 5 mg LACRISERT® administered once a day during the waking hours was compared to artificial tears used four or more times daily. Prolongation of tear film breakup time was statistically significant in two of the four studies and lessening of foreign body sensation, burning, tearing, itching, soreness, and dryness in the majority of patients during treatment with inserts as compared to artificial tears. Improvement, as measured by lessening of symptoms, by rose bengal staining, slit lamp examination of the cornea and conjunctiva, was greater in most patients with moderate to severe symptoms during treatment with LACRISERT®. Patient comfort was usually better with LACRISERT® than with artificial tears solution, and most patients preferred LACRISERT®.
In most patients treated with LACRISERT® for over one year, improvement was

observed as evidenced by lessening of symptoms generally associated with keratoconjunctivitis sicca such as burning, tearing, foreign body sensation, itching, photophobia and blurred vision.

In healthy volunteers, a thickened precorneal tear film was usually observed through the slit lamp while LACRISERT® was present in the conjunctival sac.

INDICATIONS

LACRISERT® (hydroxypropyl cellulose ocular system, USP) ophthalmic insert is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. LACRISERT® is indicated 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

DOSAGE AND ADMINISTRATION

One LACRISERT® (hydroxypropyl cellulose ocular system, USP) ophthalmic insert in each eye once daily is usually sufficient to relieve the symptoms associated with moderate to severe dry eye syndromes. Individual patients may require more flexibility in the use of LACRISERT®, some patients may require twice daily use for optimal results.

In some patients, the concomitant administration of a replacement tear solution at the time of insertion may be of benefit to assist in the dissolution of the insert and removal of debris. Saline drops may be used with LACRISERT® in cases with severe dry eyes to assist in the dissolution of the insert and removal of debris. Clinical experience with LACRISERT® indicates that in some patients several weeks may be required before satisfactory improvement of symptoms is achieved.

LACRISERT® is inserted into the inferior cul-de-sac of the eye beneath the base of the tarsus, not in apposition to the cornea.

NOTE: Occasionally LACRISERT® is inadvertently expelled from the eye, especially in patients with shallow conjunctival fornices or when the eye is rubbed. The patient should be cautioned against rubbing the eye(s) containing LACRISERT®, especially upon awakening, so as to not dislodge or expel the insert. If required, another LACRISERT® ophthalmic insert may be inserted. If experience indicates that transient blurred vision develops in an individual patient, the patient may want to remove LACRISERT® a few hours after insertion to avoid this. Another LACRISERT® ophthalmic insert may be inserted if needed.

Expulsion of undissolved inserts one to several hours after application may occur in patients with Schirmer tests of 0 mm.

If LACRISERT® causes worsening of symptoms, the patient should be instructed to inspect the conjunctival sac to make certain LACRISERT® is in the proper location, deep in the inferior cul-de-sac of the eye, beneath the base of the tarsus. If these symptoms persist, LACRISERT® should be removed and the patient should contact the physician.

CONTRAINDICATIONS

Hypersensitivity to hydroxypropyl cellulose.

PRECAUTIONS

Instructions for inserting and removing LACRISERT® (hydroxypropyl cellulose ocular system, USP) ophthalmic insert should be carefully followed. If improperly placed in the inferior cul-de-sac, LACRISERT® may result in corneal abrasion.
Because this product may produce transient blurring of vision, patients should be instructed to exercise caution when operating hazardous machinery or driving a motor vehicle.

The safety and efficacy of LACRISERT® has not been evaluated in patients with the following conditions: ocular infections or history of infection, eye region surgery or history of ocular trauma, contact lenses use, history of dendritic keratitis, intraocular diseases, severe cicatricial changes in the conjunctiva, significant corneal or conjunctival structural changes, acute ocular disease unrelated to keratoconjunctivitis sicca (KCS), and patients with evidence of recent ocular or adnexal surgery.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

ADVERSE REACTIONS

The following adverse reactions have been reported in patients treated with LACRISERT® (hydroxypropyl cellulose ocular system, USP), but were in most instances mild and transient:

Transient blurring of vision (see PRECAUTIONS)
Ocular discomfort or irritation
Matting or stickiness of eyelashes
Photophobia
Hypersensitivity
Edema of the eyelids
Hyperemia
Tearing
Foreign body sensation

PHARMACEUTICAL INFORMATION

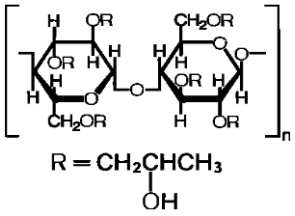
I. DRUG SUBSTANCE

Proper Name: hydroxypropyl cellulose

Chemical Name: cellulose, 2-hydroxypropyl ether

Empirical Formula: $-CH_2CHOHCH_3$

Structural Formula:



Molecular Weight: 1×10^6

Description: 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, dioxane, methanol, isopropyl alcohol (95%), dimethyl sulfoxide, and dimethyl formamide.

II. COMPOSITION

Each LACRISERT® insert is 5 mg of hydroxypropyl cellulose. LACRISERT® contains no preservatives or other ingredients. It is about 1.27mm in diameter by about 3.5 mm long.

III. STORAGE RECOMMENDATIONS

Store below 30°C.

AVAILABILITY OF DOSAGE FORMS

LACRISERT® (hydroxypropyl cellulose ocular system, USP) ophthalmic insert, a rod-shaped, watersoluble, ophthalmic preparation made of hydroxypropyl cellulose, 5 mg, is supplied as follows:

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.

Illustrated instructions are included in each package, but initially patients must be instructed in the correct method of insertion. While in the ophthalmologist's office, the patient should read the instructions, then practice insertions and removal of LACRISERT® until proficiency is achieved.

INFORMATION FOR THE PATIENT

LACRISERT®

(hydroxypropyl cellulose ocular system, USP)

FOR PROFESSIONAL USE ONLY

Please read this leaflet carefully before you start to take your medicine, some of the information in the previous leaflet may have changed. Only use on the advice of your physician. The first time you use LACRISERT®, it must be in the presence of your physician to make sure it is inserted properly.

Remember that your physician has recommended this medicine only for you. Never give it to anyone else.

What is LACRISERT®?

LACRISERT® (hydroxypropyl cellulose ocular system, USP) ophthalmic insert is a sterile, rod-shaped, ophthalmic preparation for administration inside your lower eyelid. It is about 1.27 mm in diameter by about 3.5 mm long. Each LACRISERT® is made of 5 mg of hydroxypropyl cellulose.

LACRISERT® contains no preservatives or other ingredients.

LACRISERT® is available as 5 mg ophthalmic inserts. It 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.

LACRISERT® thickens the tear film in the eye, thus lubricating and protecting the eye.

Why has my physician recommended LACRISERT®?

Your physician has recommended LACRISERT® because you have dry eyes, resulting from too little tear production.

This condition may cause your eye to become irritated. If left untreated, your condition could worsen your eyesight.

What should I know before and while taking LACRISERT®?

Who should not use LACRISERT®?

Do not use LACRISERT® if you are allergic to hydroxypropyl cellulose.

What should I tell my physician before or while using LACRISERT®?

Tell your physician about any medical problems you have or have had, and about any allergies.

In case of discomfort, make certain that LACRISERT® is properly placed deep inside the lower eyelid.

If discomfort persists or if there is a worsening of symptoms, remove the ophthalmic insert and contact your physician (see “Instructions For Removing LACRISERT®”).

Use in pregnancy and breast-feeding.

Pregnancy

You should tell your physician if you are pregnant or intend to become pregnant. Your physician will decide if you should use LACRISERT®.

Breast-feeding

You should tell your physician if you are breast-feeding or intend to breast-feed. Your physician will decide if you should use LACRISERT®.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

Can I use LACRISERT® with other medicines?

You should tell your physician about all drugs that you are using or plan to use, including those obtained without a prescription.

Saline drops may be used with LACRISERT® in cases with severe dry eyes.

Can I wear contact lenses?

LACRISERT® may be used in patients wearing contact lenses as long as LACRISERT® has dissolved prior to insertion of the contact lenses. LACRISERT® should not be inserted while the contact lenses are in the eyes. Rather, the contact lenses should be removed, then LACRISERT® placed in the cul-de-sac and allowed to dissolve prior to re-insertion of the contact lenses.

Can I drive or operate machinery while using LACRISERT®?

This product may cause temporary blurring of vision. Be cautious when driving or when operating hazardous machinery.

How should I use LACRISERT®?

Your physician will tell you about the appropriate dosage and duration of treatment. The usual dose is one LACRISERT® ophthalmic insert in each eye once daily. In some cases, physicians recommend twice daily use.

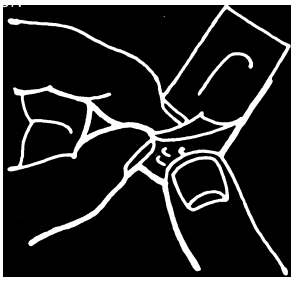
Do not change the dosage of the drug without consulting your physician. If you must stop treatment, contact your physician immediately.

Your physician will tell you how to insert and remove LACRISERT®. Afterward, follow the illustrated instructions included in each package:

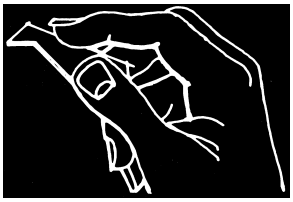
INSTRUCTIONS FOR USING LACRISERT®

1. Wash your hands thoroughly with soap and water.

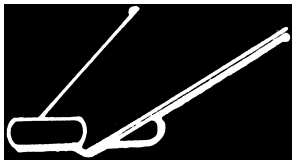
2. Each ophthalmic insert is packaged in a separate blister. Take a unit dose blister and place it on a flat surface (e.g., a table-top) with the label side up. Open the blister pocket by carefully peeling back the label area. Do not touch the ophthalmic insert with the fingers and do not let it come into contact with anything else. This will help keep it sterile.



3. Open the applicator package by peeling back the label area. Avoid touching the grooved tip of the applicator. Pick up the applicator by the wide end and rinse the top thoroughly under hot, running water. Gently shake off excess water.

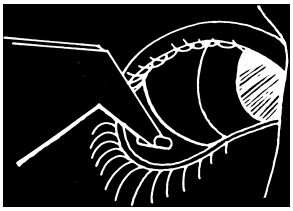


4. Hold the applicator with the tip facing down. Press the grooved tip gently into the center of the LACRISERT® ophthalmic insert. With your forefinger you may guide the applicator and apply pressure. The ophthalmic insert now adheres to the applicator.



5. Look into a mirror. Starting with the right eye, turn your head to the right so that the coloured part of the eye (iris and pupil) is close to your nose. Use your free hand to grasp the lower lid between the thumb and index finger. Pull the lid away from the eyeball and create a pocket between the lower lid and the eyeball.

6. Place the tip of the applicator containing the ophthalmic insert into the pocket. Do not touch the coloured part of your eye. Lift the applicator from the pocket. Look down, then release the lower eyelid. The ophthalmic insert should remain deep in the pocket of the eye.



7. Rinse the applicator thoroughly under hot, running water. Gently shake off visible water droplets and promptly return the applicator to the storage container.

Instructions for Removing LACRISERT®

Generally, LACRISERT® completely dissolves inside your eyelid within 24 hours. Should removal be necessary, follow these instructions:

Pull the lid away from the eyeball while looking in a mirror. Find the ophthalmic insert. Close the eyelid. Move the ophthalmic insert upward with your finger tips through the closed eyelid. Do not pull the lid away from the eyeball. In this way the ophthalmic insert will slip over the lid margin and can be removed with a clean facial tissue. Do not touch the coloured part of the eye.

So as not to dislodge or expel the insert, avoid rubbing the eye(s) containing LACRISERT®, especially upon wakening. If you do dislodge or expel LACRISERT®, you may insert another.

If LACRISERT® is improperly placed, your eye may become scratched.

What should I do in case of an overdose?

If LACRISERT® ophthalmic inserts are swallowed, contact your physician immediately.

What should I do if I miss a dose?

It is important to use LACRISERT® as recommended by your physician. If you miss a dose, use it as soon as possible. However, if it is almost time for the next dose, skip the missed dose, and go back to your regular dosing schedule.

What undesirable effects may LACRISERT® have?

Any medicine may have unintended or undesirable effects, so-called side effects.

Patients may experience temporary blurring of vision, eye discomfort or irritation, matting or stickiness of eyelashes, unusual visual sensitivity to light, redness and swelling of the eyelids, redness of the eye, allergic reactions, and tearing.
If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists remove the insert and consult a physician.

Other side effects may also occur rarely, and some of these may be serious. Ask your physician or pharmacist for more information about side effects. Both have a more complete list of side effects.

Please tell your physician or pharmacist promptly about these or any other unusual symptoms.

How can I learn more about LACRISERT® and ocular dryness?

You may obtain further information from your physician or pharmacist, who have more detailed information about LACRISERT® and your eye condition.

How long will my medicine last?

Do not use this medicine after the month and year following EXP on the container.

How should I store LACRISERT®?

Store below 30°C.

Keep all medicines safely away from children.

CAUTION: Because this product may produce transient blurring of vision, you should exercise caution when operating hazardous machinery or driving a motor vehicle.

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