PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Lotemax® Suspension

Sterile ophthalmic suspension

Composition

Each 1 ml contains:

Loteprednol etabonate 5 mg (0.5%)

For information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for use in children and infants, since there are no safety and efficacy data for this population.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lotemax Suspension is intended for the treatment of inflammatory conditions in the eye responsive to treatment with steroids.

Lotemax Suspension is also intended for treatment of inflammation after ocular surgery.

Therapeutic group:

Anti-inflammatory corticosteroid.

2. BEFORE USING THE MEDICINE

Do not use the preparation:

- If there is a known sensitivity to any of its ingredients or to other corticosteroids.
- For viral eye infections such as herpes and chickenpox.
- For eye infections caused by *Mycobacteria* or a fungus.

Special warnings regarding use of the medicine

Before treatment with Lotemax Suspension, tell the doctor if:

- You are suffering, or have suffered in the past, from impaired function of the eyes (especially glaucoma).
- You have a history of herpes simplex.

Additional warnings

- Do not swallow! This medicine is intended for external use only.
- Prolonged use of steroids may result in development of glaucoma (intraocular pressure), cataract (cloudiness of the lens of the eye), may weaken the ability of the body to fight infections, thereby increasing the risk of getting a secondary eye infection.
- Using steroids for eye treatment may cause viral diseases of the eye (such as herpes simplex) to worsen and to last longer.
- In acute purulent conditions of the eye, steroids may mask inflammation or enhance existing inflammation.
- Prolonged use of topical steroids may result in perforation of the cornea in areas where the cornea is thinner due to disease.
- Fungal infections of the cornea may develop during prolonged use of corticosteroids and in cases of corneal ulceration treated in the past/being treated with steroids. If necessary, a culture may be taken to check for presence of fungi.
- The use of steroids after cataract surgery may cause a delay in healing time.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- **Do not wear soft contact lenses when using this preparation since the preparation contains the preservative benzalkonium chloride which may be absorbed by these lenses.** The lenses should be removed before using the preparation and can be reinserted at least 15 minutes after installation of the medicine into the eye. It is recommended to avoid use of contact lenses if you suffer from an eye inflammation.

If you are taking, or have recently taken, other medicines, including non-prescription medicines, herbal medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding

Consult a doctor or pharmacist before using the medicine if you are pregnant, think you are pregnant, are planning to become pregnant or are breastfeeding.

Use in children

This medicine is not intended for use in children and infants.

Driving and operating machinery

Use of eye drops may cause temporary blurring of vision. Do not drive or use dangerous machinery until your vision is clear.

Important information about some of the ingredients of the medicine

The medicine contains the preservative benzalkonium chloride, which may be absorbed by soft contact lenses and change their color. Contact lenses should be removed before using the medicine and put back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you suffer from dry eyes, or corneal disorders.

If you feel abnormal eye sensation, stinging or pain in the eye after using the medicine, refer to your doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only.

Shake well before use.

Wash your hands thoroughly, tilt back your head or lie down on a bed. With the aid of the index finger, pull the lower eyelid slightly away from the eye. Instill the medicine into the gap that forms and keep your eyes closed for 1-2 minutes. Do not blink. To prevent contamination of the suspension – take care not to allow the tip of the bottle to come into contact with any surface, including the finger or the eye, and close the bottle tightly after use.

The usual dosage is generally:

Diseases responsive to treatment with steroids

Instill 1-2 drops into the conjunctival sac of the affected eye 4 times a day. If necessary, the initial dosage can be increased during the first week, up to one drop every hour.

Post-surgical inflammation

Instill 1-2 drops into the conjunctival sac of the operated eye 4 times a day, beginning 24 hours after surgery, and continue throughout the first 2 weeks of the post-surgical period.

This medicine is not intended for use in children and infants.

Do not exceed the recommended dose.

If there is no improvement in your condition within two days, refer to the doctor. The doctor may want to reevaluate your condition.

If you are using Lotemax Suspension for 10 days or more, intraocular pressure should be monitored.

Use this medicine at specified time intervals, as determined by the attending doctor.

If you accidentally took a higher dosage of the medicine, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember, but never take two doses together. Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment before consulting a doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of the preparation may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if some of the following side effects occur:

- Blurred vision or any change in vision
- Redness or swelling of the eye
- Conjunctival edema (swelling of the membrane covering the white part of the eye)
- Ocular discharge
- Ocular discomfort
- Irritation or pain
- Sensitivity of the eye to light
- Redness of the eyelid or of the inner lining of the eyelid
- Tiny bumps on the inner lining of the eyelid
- Corneal abnormalities.

Additional side effects

Upon prolonged use of corticosteroids for ocular treatment the following side effects may occur:

- Increased intraocular pressure (glaucoma)
- Damage to the optic nerve
- Defects in visual acuity and visual fields
- Cataract formation
- Secondary ocular infections, such as herpes simplex
- Perforation of the cornea in areas where the cornea is thinner due to disease.

Other side effects that may occur usually do not require medical intervention. These side effects usually pass during the course of treatment and after adaptation to the preparation.

If the following side effects do not pass and/or are bothersome, refer to the attending doctor:

- Burning when instilling the medicine into the eye
- Dry eyes
- Sensation of foreign body in the eye
- Headache
- Itching
- Runny nose
- Sore throat
- Tearing eyes.

Some of the side effects listed above resemble the symptoms of the inflammation from which you suffer.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Keep the bottle in an upright position, at a temperature between 15°C-25°C. Do not freeze.

Do not use this medicine for more than 28 days after first opening the bottle.

Even when packed/stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medicines in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Glycerin, povidone, tyloxapol, benzalkonium chloride solution, edetate disodium dihydrate, hydrochloric acid, sodium hydroxide, purified water.

What the medicine looks like and the contents of the package

A milky white suspension packaged in 2.5, 5 and 10 ml plastic vials with a controlled drop tip.

License Holder

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

Name of Manufacturer and its Address

Bausch & Lomb Incorporated, USA.

This leaflet was revised in October 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 141.93.31617