The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in September 2017

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

The medicine is dispensed with a doctor's prescription only.

Lotemax® Gel

Sterile Ophthalmic Gel

Composition

Each 1 g contains:

Loteprednol Etabonate 5 mg (0.5%)

Also contains the preservative benzalkonium chloride 0.003%

For the list of inactive ingredients in the preparation, see section 6 - "Further Information".

Read this 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 Gel is intended for the treatment of inflammatory conditions and pain in the eyes following ocular surgery.

Therapeutic group:

Anti-inflammatory corticosteroid.

2. BEFORE USING THE MEDICINE

☒ Do not use the preparation if:

- You have a known sensitivity to any of its ingredients or to other corticosteroids.
- Do not use this medicine for viral eye inflammations such as herpes and chicken pox.
- Do not use this medicine for eye infections caused by *Mycobacterium* or a fungus.

Special warnings regarding use of the medicine

❗ Before treatment with the medicine, 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), may lower the ability of the body to fight infections, thereby increasing the risk of getting a secondary eye infection.
- Use of corticosteroids may lead to development of a cataract.
- Using steroids for eye treatment may cause viral diseases of the eye (such as herpes simplex) to worsen or to be prolonged.
- In acute purulent conditions of the eye, steroids may mask inflammation or enhance existing inflammation.
- Use of steroids for eye treatment 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. Presence of a fungal infection in cases of chronic corneal ulceration forming after or during treatment with steroids should be considered.
- 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.**

❗ 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 use of machinery

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

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.

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

The usual dosage is generally:

Invert the closed bottle and shake once to fill the tip of the dropper before instilling the drops.

Starting from the day after surgery, instill 1-2 drops of Lotemax into the conjunctival sac of the affected eye, 4 times a day, for two weeks following surgery.

Be sure that the tip of the bottle does not come into contact with any surface, including with the finger or the eye and close the bottle tightly after use.

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

Do not exceed the recommended dose.

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

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

If you accidentally took an overdose 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, do not stop treatment before consulting a doctor.

How can you contribute to the success of the treatment?

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 this 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.

The most common side effects

- Inflammation of the iris
- Ocular pain
- Sensation of a foreign object in the eye.

Additional side effects

Upon 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.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (Expiry 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 below 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 this 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 99.7%, boric acid, propylene glycol, polycarbophil, edetate disodium dihydrate, sodium chloride, tyloxapol, water for injection and sodium hydroxide to adjust pH.

PRESERVATIVE: benzalkonium chloride 0.003%.

What the medicine looks like and the contents of the package

5 g gel packaged in white plastic 10 ml bottles, with a white dropper tip and a pink cover.

License Holder

Abic Marketing Ltd.,
P.O.B. 8077, Netanya.

Manufacturer and its address

Bausch & Lomb Incorporated, Florida, USA

Marketed by

Teva Pharmaceutical Industries Ltd.
P.O.B. 3190, Petah-Tikva

This leaflet was checked and approved by the Ministry of Health in September 2017

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 159.22.34925.00

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LOTE GEL PL SH 110218