

BAUSCH + LOMB

PART #: 9218705-9218805 SPEC: L-3011 / L-3111

DESCRIPTION: Lotemax, Insert, Ireland/UK

SPECIAL INSTRUCTIONS: DIELINE DOES NOT PRINTCOLORS: **BLACK** PRINT PER SPECIFICATION BARCODES VERIFIED

PRINTED BARCODES MUST BE VERIFIED READABLE AND ACCURATE BY VENDOR TO THE HUMAN READABLE INDICATED ON ARTWORK.

BAUSCH+LOMB, 8500 HIDDEN RIVER PARKWAY, TAMPA, FL 33637 - 813-866-2485

2/8/2021
2/23/2021

REGULATORY MUST ANSWER QUESTIONS BELOW BEFORE ARTWORK CAN BE FINALIZED:

YES NO DO PROPOSED CHANGES REQUIRE HEALTH AUTHORITY APPROVAL PRIOR TO IMPLEMENTATION WITH COMMERCIAL PRODUCT?
IF YES, PROVIDE TYPE OF FILING/VARIATION REQUIRED, STATUS OF FILING AND OTHER DETAILS IN THE COMMENT BOX BELOW.

COMMENTS:

BAUSCH + LOMB**Lotemax® 0.5% w/v**Eye Drops, Suspension
Loteprednol Etabonate

Package leaflet: Information for the user

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lotemax is and what it is used for
2. What you need to know before you use Lotemax
3. How to use Lotemax
4. Possible side effects
5. How to store Lotemax
6. Contents of the pack and other information

1. What Lotemax is and what it is used for

Lotemax is an eye drop suspension.
Lotemax is used to treat inflammation of the eye, after surgery.
Sometimes the eye may become inflamed (red and painful). Loteprednol etabonate is one of a group of medicines called corticosteroids. It acts by reducing inflammation and eases the symptoms. Because it is used in low doses directly where it is needed, its action is only at this place.

2. What you need to know before you use Lotemax**Do not use Lotemax:**

- if you are allergic to the active substance (loteprednol) or any of the other ingredients of this medicine (listed in section 6).
- if you have been allergic to any other corticosteroid.
- if you have eye diseases caused by viruses such as herpes simplex, vaccinia, and varicella.
- if you have eye diseases caused by mycobacterium and fungi.
- If you are breast-feeding.

Warnings and precautions

- Tell your doctor if you already have glaucoma.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Tell your doctor if pain develops, or if redness, itching, or inflammation gets worse.
- See your doctor if your symptoms do not get better within 2 days. He/she may want to re-evaluate your condition.
- You should not use Lotemax longer than 10 days without having the pressure in your eye checked by your doctor.
- Long-term use of Lotemax or other eye drops that contain steroids, may result in glaucoma or raised pressure in the eye, which can cause damage to the optic nerve, problems with vision, and cataracts.
- Long-term use of Lotemax or other eye drops that contain steroids, may lower your ability to fight infections and may increase your chance of getting an eye infection including herpes simplex.
- Using steroid eye drops like Lotemax may make viral diseases of the eye worse and last longer.

Contact lenses

Wearing contact lenses is not recommended after cataract surgery. If you normally wear contact lenses, your doctor will recommend you use glasses for a time following cataract surgery. This is to allow your eyes to recover from the procedure. Your doctor will advise you when you can use contact lenses again (see also "Lotemax contains benzalkonium chloride").

Other medicines and Lotemax

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially, tell your doctor if you use:

- medicines known as anticholinergics (used to treat a variety of conditions, e.g. gastrointestinal cramps, muscular spasms, urge incontinence or asthma).
- eye drops for the treatment of high pressure in the eye.

Some medicines may increase the effects of Lotemax and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
It is possible that you may still receive Lotemax, but it is also possible that an alternative may be used.
Lotemax should not be used when breast-feeding.

Driving and using machines

Eye drops can cause your vision to be blurred. This usually passes quickly. Do not drive or use machines until your vision is clear.

Lotemax contains benzalkonium chloride

This medicine contains 0.0152 mg benzalkonium chloride in each dosage unit (2 drops) which is equivalent to 0.20 mg/1 ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Lotemax

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose for adults and elderly is one to two drops four times daily. Treatment with Lotemax normally begins 24 hours after surgery and continues for two weeks.

Use in adults

- Shake Lotemax well before using.
- Look upwards and gently pull down the lower eyelid of the affected eye(s).
- Apply one to two drops of Lotemax into the gap between your eyeball and eyelid, four times a day or as directed by your doctor.
- Do not allow the tip of the dropper to touch any surface because this may contaminate the medicine.
- The bottle should be closed immediately after use.
- Your doctor will tell you how long your treatment with Lotemax will last.
- Do not stop treatment without talking with your doctor.

Use in children and adolescents

Lotemax should not be used in children and adolescents until further data becomes available.

If you use more Lotemax than you should

Tell your doctor or a pharmacist.

If you forget to use Lotemax

Do not take a double dose to make up for a forgotten dose.
Wait until the next dose and then continue as before.

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If you stop using Lotemax

Always use this medicine exactly as your doctor has told you. Do not stop using Lotemax without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following symptoms: redness, itching or swelling of the membrane covering the white part of the eye and/or eyelid(s) or general symptoms such as difficulty breathing, difficulty swallowing, flushing or redness of the face and swelling of the face or tongue **you should stop using this medicine and seek immediate medical advice**. These could be the signs of severe allergic reaction.

As you may need urgent medical treatment, you should also **contact your doctor immediately** if you notice any of the following side effects:

- Worsened pain in the eye, especially when exposed to bright light and redness in the eye whilst using this medicine. This may be a result of inflammation of the coloured part of the eye, called iritis - uncommon side effect (may affect up to 1 in 100 people).
- Lump or thickening in an area of the breast, change in the size, shape or feel of a breast, swelling or lump in your armpit or a change in the shape of your nipple. These may be symptoms of breast cancer, which is rare side effect (may affect up to 1 in 1,000 people).
- Involuntary muscle contraction (muscle twitching) - rare side effect (may affect up to 1 in 1,000 people).
- Nervousness - rare side effect (may affect up to 1 in 1,000 people).
- Noise (ringing) in the ears (tinnitus) - rare side effect (may affect up to 1 in 1,000 people).
- Chest pain - rare side effect (may affect up to 1 in 1,000 people).

The side effects listed below may also occur during treatment with this medicine:

Common side effects (may affect up to 1 in 10 people):

- Effects in the eye:* abnormal vision, conjunctiva swelling, conjunctivitis, eye irritation, eye pain, fine elevations on the conjunctiva, light sensitivity, ocular inflammation, inflammation of the cornea and conjunctiva, ocular infection and lens opacification.
- General side effects:* headache.

Uncommon side effects (may affect up to 1 in 100 people):

- Effects in the eye:* abnormal vision, conjunctiva swelling, conjunctivitis, eye irritation, eye pain, fine elevations on the conjunctiva, light sensitivity, ocular inflammation, inflammation of the cornea and conjunctiva, ocular infection and lens opacification.
- General side effects:* fatigue, running nose and sore throat.

Rare side effects (may affect up to 1 in 1,000 people):

- General side effects:* migraine, taste change, sensation of vertigo, numbness, chills, fever and pain, cough, urinary tract infection or inflammation, urticaria, rash, dry skin, eczema, diarrhoea, nausea and vomiting, weight gain.

Not known: frequency cannot be estimated from the available data:

- Effects in the eye:* blurred vision.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
 Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lotemax

Keep this medicine out of the sight and reach of children.

Store the container in an upright position.

Do not store above 25°C. Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton and bottle after expiry. The expiry date refers to the last day of the month.

Throw away any solution 28 days after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

DO NOT USE IF PROTECTIVE SEAL IS BROKEN

6. Contents of the pack and other information

What Lotemax contains

- The active ingredient is Loteprednol Etabonate. Each ml contains 5 mg (0.5%) Loteprednol Etabonate.
- The other ingredients are Disodium Edetate, Glycerol, Purified Water and Tyloxapol.
- Benzalkonium Chloride (0.01%) is added as a preservative.
- Sodium Hydroxide and/or Hydrochloric Acid are added to adjust the pH.

What Lotemax looks like and contents of the pack

Lotemax is a milky-white eye-drops suspension.

Lotemax is available in bottles containing 2.5 mL, 5 mL or 10 mL.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

UK: Bausch & Lomb GmbH
 Brunsbütteler Damm 165/173
 13581 Berlin
 Germany

IE: Dr. Gerhard Mann chem.-pharm. Fabrik GmbH
 Brunsbütteler Damm 165/173
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This leaflet was last revised in: February 2021

Other sources of information

For any information about this medicine, please contact Bausch & Lomb,
 106 London Road, Kingston-Upon-Thames, Surrey, KT2 6TN, UK.

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