

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S4**LOTEMAX® CO eye drops, suspension****Loteprednol etabonate 0,5 % and Tobramycin 0,3 %****Read all of this leaflet carefully before you start using LOTEMAX CO**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LOTEMAX CO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LOTEMAX CO is and what it is used for
2. What you need to know before you use LOTEMAX CO
3. How to use LOTEMAX CO
4. Possible side effects
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1. What LOTEMAX CO is and what it is used for

LOTEMAX CO is an eye drops suspension containing a combination of an antibiotic and a corticosteroid. It is used to treat inflammatory conditions of the eye, where there is also a bacterial infection, or the risk of a bacterial infection.

2. What you need to know before you use LOTEMAX CO

Do not use LOTEMAX CO:

- If you are hypersensitive (allergic) to loteprednol etabonate or tobramycin, or any of the other ingredients of LOTEMAX CO (listed in section 6).
- If you are allergic to other corticosteroids.
- If you have a viral disease of the cornea (the cornea is the transparent front part of the eye), or
- if you have a viral disease of the conjunctiva (the conjunctiva covers the sclera which is the white part of the eye and lines the inside of the eyelids),
- if you have a mycobacterial infection (related to TB) of the eye and
- if you have fungal disease of eye structures.

Warnings and precautions

Take special care with LOTEMAX CO:

- **LOTEMAX CO should be used as eye drops only, it should not be injected into the eye or other tissue.**
- You should consult your doctor if you develop pain, redness or itching, or if the inflammation becomes aggravated.
- You should not wear soft contact lenses while using LOTEMAX CO.
- If you have glaucoma, your intraocular pressure should be monitored if LOTEMAX CO is used for 10 days or longer.
- After cataract surgery, the use of ocular steroids may delay healing and increase the incidence of bleb formation – which is a fluid bubble on the surface of the eye. Your doctor should examine your eyes regularly.

- If your symptoms do not improve after 2 days, you should consult with your medical practitioner.
- If you have a history of herpes simplex, as the use of LOTEMAX CO may increase the severity of viral infections (including herpes simplex).
- Your doctor should monitor you for fungal infections, as long-term use of LOTEMAX CO may cause a fungal infection to develop.
- If you experience hypersensitivity towards LOTEMAX CO, stop using the medicine and inform your medical practitioner.

Other medicines and LOTEMAX CO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Your doctor should monitor you carefully if you are taking certain other antibiotic medicines while using LOTEMAX CO.

If LOTEMAX CO is used with certain other medicines, it may cause an increase in the pressure in your eye.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

LOTEMAX CO should not be used by pregnant and breastfeeding women.

Driving and using machines

LOTEMAX CO may cause side effects in your eyes. If you have abnormal or blurred vision at instillation, you should wait until your vision clears before driving or using machinery.

It is not always possible to predict to what extent LOTE MAX CO may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which LOTE MAX CO affects you.

LOTEMAX CO contains benzalkonium chloride

This medicine contains benzalkonium chloride 0,1 mg/1 ml as preservative and therefore you must go for regular ophthalmological examinations.

This is due to the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved ophthalmological preparations.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the 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 LOTE MAX CO

Do not share medicines prescribed for you with any other person.

Always use LOTE MAX CO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

SHAKE VIGOROUSLY BEFORE USE.

The usual dose is: one or two drops in the conjunctival sac of the affected eye(s) every four to six hours.

Do not let the tip of the bottle touch your eye, fingers or any other surfaces.

Do not stop treatment early, because LOTEMAX CO contains an antibiotic.

If you have the impression that the effect of LOTEMAX CO is too strong or too weak, tell your doctor or pharmacist.

If you use more LOTEMAX CO than you should

Overdosage of this medicine is unlikely to occur because it is used in your eyes only.

In the event of overdosage, or if someone accidentally swallowed the eye drops, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use LOTEMAX CO

Do not instil a double dose into your eyes to make up for forgotten individual doses.

Continue with your next dose as normal.

4. Possible side effects

LOTEMAX CO can have side effects.

Not all side effects reported for LOTEMAX CO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LOTEMAX CO, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- Burning or stinging upon instillation,

- blurred vision,
- conjunctivitis,
- increased tearing,
- eye pain,
- infection,
- inflammation of the small oil glands in our eyelids (meibomianitis),
- redness or swelling of your eyelids,
- increased intraocular pressure,
- foreign body sensation,
- eye strain,
- eyes become red, watery and sensitive to light (these are symptoms of keratitis),
- headache,
- nausea, or
- rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

You can also report side effects directly to the company, using the following e-mail address:

PV-SouthAfrica@bausch.com

By reporting side effects, you can help provide more information on the safety of LOTEMAX CO.

5. How to store LOTEMAX CO

Store all medicines out of reach of children.

- Store upright at or below 30 °C.
- Do not freeze.
- Do not use after the expiry date stated on the carton and bottle.
- Do not use for more than 28 days after opening.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOTEMAX CO contains

The active substances are loteprednol etabonate 5 mg/mL (0,5 % *m/v*) and tobramycin 3 mg/mL (0,3 % *m/v*).

The preservative is benzalkonium chloride 0,1 mg/mL (0,01 % *m/v*).

The other ingredients are edetate disodium, glycerine, povidone, purified water, sodium hydroxide and/or sulfuric acid (for pH adjustment) and tyloxapol.

What LOTEMAX CO looks like and contents of the pack

LOTEMAX CO is an eye drops suspension. It is a white to off-white, milky suspension.

LOTEMAX CO is supplied as a 5 mL fill volume in a 7,5 mL white, round, low density polyethylene plastic bottle with a white controlled drop tip and a white polypropylene cap, packed in a printed outer carton.

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.

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