PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LOTEMAX® OPHTHALMIC GEL

Loteprednol etabonate 0,5 % eye gel

Read all of this leaflet carefully before you start using LOTEMAX OPHTHALMIC GEL

- 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 OPHTHALMIC GEL has been prescribed for you or your child 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

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1. What LOTEMAX OPHTHALMIC GEL is and what it is used for

LOTEMAX OPHTHALMIC GEL is a corticosteroid used for the treatment of post-operative inflammation and pain following eye surgery.

2. What you need to know before you use LOTEMAX OPHTHALMIC GEL

Do not use LOTEMAX OPHTHALMIC GEL if you:

- are allergic to loteprednol etabonate or any of the other ingredients of LOTEMAX OPHTHALMIC GEL (listed in section 6),
- are allergic to other corticosteroids,
- have a viral disease of the cornea (the cornea is the transparent front part of the eye), or
- 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),
- have a mycobacterial infection (related to TB) of the eye and
- fungal disease of eye structures.

Warnings and precautions

Take special care with LOTEMAX OPHTHALMIC GEL as:

- LOTEMAX OPHTHALMIC GEL as stated contains a corticosteroid, of which prolonged use may result in glaucoma (elevated pressure in the eye) with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Therefore, it should be used with caution in the presence of glaucoma.

- Prolonged use of corticosteroids may suppress your immune response and increase the risk of secondary eye infections.
- The active ingredient which is a corticosteroid can, if you suffer from a disease which caused thinning of your cornea or sclera, perforate your cornea or sclera.
- The active ingredient which is a corticosteroid can, in acute purulent conditions of the eye, mask the infection or enhance existing infections.
- The use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye, including *Herpes simplex*, therefore if you are aware that you have a history of *Herpes simplex* infection you must tell your doctor about it.
- The use of ocular steroids after cataract surgery may delay healing and increase the incidence of bleb formation - which is a fluid bubble on the surface of the eye.
- You should not wear contact lenses when using LOTEMAX OPHTHALMIC GEL.

Children and adolescents

LOTEMAX OPHTHALMIC GEL can be used in adults (including the elderly) and in children. The safety and effectiveness of LOTEMAX OPHTHALMIC GEL have been established in paediatric patients from birth to 11 years of age.

Other medicines and LOTEMAX OPHTHALMIC GEL

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

If LOTEMAX OPHTHALMIC GEL 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 OPHTHALMIC GEL and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV, cobicistat).

Should you notice any undesirable effects, please consult your doctor, pharmacist or other healthcare professional, for advice.

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 OPHTHALMIC GEL should not be used by pregnant and breastfeeding women.

Driving and using machines

LOTEMAX OPHTHALMIC GEL 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 LOTEMAX OPHTHALMIC GEL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LOTEMAX OPHTHALMIC GEL affects you.

LOTEMAX OPHTHALMIC GEL contains benzalkonium chloride

LOTEMAX OPHTHALMIC GEL contains Benzalkonium chloride 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 clear layer at the front of the eye). If you feel abnormal sensation, stinging or pain in the eye after using LOTEMAX OPHTHALMIC GEL, talk to your doctor.

3. How to use LOTEMAX OPHTHALMIC GEL

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

Always use LOTEMAX OPHTHALMIC GEL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Invert the closed bottle and shake once to fill the tip before instillation.
- Do not let the dropper tip touch your eye, fingers or any other surface.
- Compress the inner corner of your eye for at least 2 minutes during and following instillation.

The usual dose is: one to two drops into the conjunctival sac of the affected eye four times daily.

Your treatment will start the day after surgery and continue for two weeks. Do not stop treatment early.

If you use more LOTEMAX OPHTHALMIC GEL than you should

In the event of overdosage, for example instilling the complete content of the eye drop bottle in your eye, the eye should be thoroughly washed with clean lukewarm water and you should go to the nearest hospital for observation.

If you forget to use LOTEMAX OPHTHALMIC GEL

You must use LOTEMAX OPHTHALMIC GEL as prescribed. However, if you have missed a dose or forgotten to use your eye drops, as soon as you remember you should use the next dose and adjust the time period between the remaining doses to add up to four doses in a 24 hour time period.

4. Possible side effects

LOTEMAX OPHTHALMIC GEL can have side effects.

Not all side effects reported for LOTEMAX OPHTHALMIC GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LOTEMAX OPHTHALMIC GEL, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor in you notice any of the following in your eyes:

Frequent side effects

- Eye pain
- Swelling of the eyelids (in children)

Less frequent side effects

- Inflammation in the eye
- Increased lacrimation (tearing)
- Photophobia (sensitivity to light)
- Eye irritation or discomfort
- Itching of the eyes or eyelids

- Foreign body sensation
- Dry eye
- Increase intra-ocular pressure
- Blurred vision
- Eye redness
- Eye swelling

Tell your doctor if you experience any of the following other side effects:

Less frequent side effects

- Facial rash
- Dry mouth
- Hypersensitivity (allergic reaction)
- Headache
- Nausea

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 OPHTHALMIC GEL.

5. How to store LOTEMAX OPHTHALMIC GEL

Store all medicines out of reach of children.

Store upright at or below 25 °C.

Discard any remaining eye gel within 28 days of first opening the dropper bottle.

Do not store in bathrooms.

Do not use after the expiry date stated on the container.

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 OPHTHALMIC GEL contains

The active substance is Loteprednol etabonate 5 mg per g (0,5 % *w/w*).

The preservative is benzalkonium chloride 0,003 % *w/w*.

The other ingredients are boric acid, edetate disodium dihydrate, glycerine, polycarbophil, propylene glycol, sodium chloride, sodium hydroxide (for pH adjustment), tyloxapol, and water for injection.

What LOTEMAX OPHTHALMIC GEL looks like and contents of the pack

LOTEMAX OPHTHALMIC GEL is a sterile, white to off-white gel.

LOTEMAX OPHTHALMIC GEL is supplied in a fill weight of 5 g in a 10 ml white, low density polyethylene plastic bottle with a white controlled drop tip and pink 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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