1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LOTEMAX OPHTHALMIC SUSPENSION

Loteprednol etabonate 0,5 % eye drops, suspension

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

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

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

Your doctor has prescribed LOTEMAX OPHTHALMIC SUSPENSION to treat your eye condition which is **allergic conjunctivitis** – which is an inflammation of the conjunctiva, (the conjunctiva covers the sclera which is the white part of the eye and lines the inside of the eyelids) or **acute anterior chamber uveitis** – which is an inflammation of the middle layer of the eye, termed the uvea.

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

Do not use LOTEMAX OPHTHALMIC SUSPENSION if you

- are allergic to loteprednol etabonate or any of the other ingredients of LOTEMAX OPHTHALMIC SUSPENSION (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 SUSPENSION as

- LOTEMAX OPHTHALMIC SUSPENSION 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.

- LOTEMAX OPHTHALMIC SUSPENSION 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* 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.

Other medicines and LOTEMAX OPHTHALMIC SUSPENSION

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

If you are taking other medication on a regular basis, including complementary or traditional medicines, the use of LOTEMAX OPHTHALMIC SUSPENSION with this medication may

cause undesirable interactions unknown to you. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines may increase the effects of LOTEMAX OPHTHALMIC SUSPENSION and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat). Should you notice any undesirable effects, please consult your doctor, pharmacist or other healthcare professional, for advice.

Pregnancy and breastfeeding

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 SUSPENSION should not be used by pregnant and breastfeeding women.

Driving and using machines

LOTEMAX OPHTHALMIC SUSPENSION is not expected to affect your ability to drive a car or operate machinery.

It is not always possible to predict to what extent LOTEMAX OPHTHALMIC SUSPENSION 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 SUSPENSION affects you.

3. How to use LOTEMAX OPHTHALMIC SUSPENSION

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

SHAKE VIGOROUSLY BEFORE USING.

Allergic conjunctivitis:

Apply one drop of LOTEMAX OPHTHALMIC SUSPENSION into the conjunctival sac of the affected eye(s) four times daily. Treatment for allergic conjunctivitis should not exceed six weeks.

Acute anterior chamber uveitis:

Apply one drop of LOTEMAX OPHTHALMIC SUSPENSION into the conjunctival sac of the affected eye(s) four times daily. During the initial treatment within the first week, the dosing may be increased up to one drop every hour, if necessary.

DO NOT SHARE YOUR MEDICATION WITH ANY OTHER PERSON.

If you use more LOTEMAX OPHTHALMIC SUSPENSION 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 SUSPENSION

You must try to use LOTEMAX OPHTHALMIC SUSPENSION 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 SUSPENSION can have side effects.

Tell your healthcare provider right away if you get one or more of these symptoms:

Side-effects of the eyes such as

- abnormal vision or a blurry vision,
- chemosis - *which is the swelling (or oedema) of the conjunctiva.*
- discharge,
- dry eye,
- epiphora – *which is an excessive tear production resulting from an irritation of the eye or foreign body sensation,*
- itching, infection and photophobia – *which is a symptom of abnormal intolerance to visual perception of light*

Reactions associated with ophthalmic steroids include -

- An increase in the eye pressure, which may be associated with nerve damage that can result in visual loss or disturbances.
- It can also cause cataract formation.
- Secondary eye infection from pathogens including herpes simplex which causes cold sores, and the formation of small holes/perforation of the eye where there is thinning of the cornea or sclera.

The following side-effects have also been noticed and you should tell you doctor if they become bothersome:

- Headache, rhinitis – *stuffy nose* and pharyngitis *which is an inflammation of the throat*
- A burning sensation on instillation is considered normal.
- Other ocular side-effects can include irritation, pain, red eyelids and infection.

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

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 or, pharmacist or nurse. You can also report side effects to the Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com, or directly to SAHPRA using an ADR reporting form or the e-reporting portal available on SAHPRA's website: https://www.sahpra.org.za/health-products-vigilance/.

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

5. How to store LOTEMAX OPHTHALMIC SUSPENSION

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Store upright. Store at or below 25 °C. Do not freeze.

Discard any remaining eye suspension 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 SUSPENSION contains

Each ml of the eye drops contains the active ingredient Loteprednol etabonate 5,00 mg (0,5 % *m/v*) and Benzalkonium chloride 0,01 % *m/v* as preservative.

LOTEMAX OPHTHALMIC SUSPENSION also contains Edetate disodium dihydrate, glycerin, povidone, purified water, tyloxapol, and possible small amounts of diluted hydrochloric acid and diluted sodium hydroxide for pH adjustment.

What LOTEMAX OPHTHALMIC SUSPENSION looks like and contents of the pack

LOTEMAX OPHTHALMIC SUSPENSION is a milky white suspension.

LOTEMAX OPHTHALMIC SUSPENSION is provided in a white plastic dropper bottle containing either 2,5 or 5 or 10 or 15 ml of suspension.

Holder of Certificate of Registration

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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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