1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

LOTEMAX OPHTHALMIC SUSPENSION

Loteprednol etabonate 0,5 % eye drops, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains;

Loteprednol etabonate 5,00 mg (0,5 % *m/v*) as the active ingredient

Benzalkonium chloride 0,01 % *m/v* as the preservative

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension

LOTEMAX OPHTHALMIC SUSPENSION is a milky white suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

LOTEMAX OPHTHALMIC SUSPENSION is indicated for the treatment of allergic conjunctivitis and acute anterior chamber uveitis.

4.2 Posology and method of administration

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.

4.3 Contraindications

LOTEMAX OPHTHALMIC SUSPENSION is contraindicated in viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and also in mycobacterial infections of the eye and fungal diseases of ocular structures.

LOTEMAX OPHTHALMIC SUSPENSION is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation (see **6.1 List of excipients**) and to other corticosteroids.

4.4 Special warnings and precautions for use

Warnings

As 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 cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask the infection or enhance existing infections.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Paediatric population

The safety and effectiveness of LOTEMAX OPHTHALMIC SUSPENSION in paediatric patients have not been established.

Special precautions

For ophthalmic use only. The initial prescription and renewal of the medication order beyond 14 days should be made by a medical doctor only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated. If LOTEMAX OPHTHALMIC SUSPENSION is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncooperative patients (see **Warnings**). Caution is advised on the use of LOTEMAX OPHTHALMIC SUSPENSION in patients with glaucoma. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If pain develops, redness, itching or inflammation become aggravated, the patient should be advised to consult a medical doctor. As with all ophthalmic preparations containing benzalkonium chloride, the patients should be advised not to wear contact lenses when using LOTEMAX OPHTHALMIC SUSPENSION.

4.5 Interaction with other medicines and other forms of interaction

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of LOTEMAX OPHTHALMIC SUSPENSION in pregnancy has not been established.

Teratogenic effects: Loteprednol etabonate has been shown to be embryotoxic and teratogenic when administered to animals.

Breastfeeding

Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects. Mothers on treatment with LOTEMAX OPHTHALMIC SUSPENSION should not breastfeed their babies.

4.8 Undesirable effects

Eye disorders

Very common (≥1/10) to common (≥1/100<1/10):

Ocular side-effects occurring in 5 – 15 % of the patients treated with loteprednol etabonate ophthalmic suspension (0,2 % - 0,5 %) in clinical studies include abnormal vision / blurring, burning on instillation, chemosis, discharge, dry eye, epiphora, foreign body sensation, itching, infection and photophobia. Other ocular side-effects occurring in less than 5 % of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis,

ocular irritation / pain / discomfort, papillae and uveitis. Some of these events were similar to the underlying ocular disease being studied.

The following side-effects have been reported but the frequencies are unknown:
Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Vascular disorders

Very common (≥1/10)

Headache

Respiratory, thoracic and mediastinal disorders

Very common (≥1/10)

Rhinitis and pharyngitis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk of the medicine. Health care providers are asked to report any suspected adverse reactions 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/

4.9 Overdose

See **4.4 Special warnings and precautions for use** and **4.8 Undesirable effects**.

Treatment is supportive and symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.2 Ophthalmic preparations with corticosteroids.

LOTEMAX OPHTHALMIC SUSPENSION is a corticosteroid. Corticosteroids *in vitro* inhibit the inflammatory response.

5.2 Pharmacokinetic properties

Loteprednol etabonate is lipid soluble which enhances its penetration into cells. It undergoes extensive metabolism to inactive carboxylic acid metabolites. Plasma levels of loteprednol etabonate and cortienic acid etabonate its primary, inactive metabolite, were below the limit of quantification (1 ng/ml).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride (preservative)

Edetate disodium dihydrate

Glycerin

Povidone

Purified water

Tyloxapol

Possible small amounts of diluted hydrochloric acid and diluted sodium hydroxide (for pH adjustment)

6.3 Shelf life

Unopened, the product shelf life is 24 months.

Once the bottle is opened, it may be stored for a maximum of 28 days.

6.4 Special precautions for storage

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.

KEEP OUT OF THE REACH OF CHILDREN

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

37/15.2/0588

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10 DATE OF REVISION OF THE TEXT

13 August 2020

NAMIBIA

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