CLEAN PROFESSIONAL INFORMATION

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME AND DOSAGE FORM

FML® Liquifilm® Sterile Eye Suspension

COMPOSITION

FML® Liquifilm® Sterile Eye Suspension contains:

Fluorometholone 1,0 mg/ml

Liquifilm® (polyvinyl alcohol) 14 mg/ml

Preservative:

Benzalkonium chloride 0,004 % m/v

The other ingredients are edetate disodium, polysorbate 80, sodium phosphate dibasic heptahydrate and sodium phosphate monobasic monohydrate, sodium chloride and purified water.

PHARMACOLOGICAL CLASSIFICATION

A 15.2 Ophthalmic preparations with corticosteroids

PHARMACOLOGICAL ACTION

Fluorometholone is an anti-inflammatory steroid. Glucocorticoids inhibit the oedema, fibrin deposition, capillary dilation, and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation. Adrenocorticoids and their derivatives are capable of producing a rise in intraocular pressure.

INDICATIONS

For steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

CONTRA-INDICATIONS

FML® is contra-indicated in patients with hypersensitivity to fluorometholone or to any other components of the product.

FML® is contra-indicated in viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella infection of the eye, tuberculosis of the eye and fungal diseases of ocular structures.

WARNINGS AND SPECIAL PRECAUTIONS

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 ophthalmologic preparations cannot be excluded, regular ophthalmologic 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.

Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Steroid medication in the treatment of herpes simplex keratitis requires great caution: frequent slit-lamp microscopy is mandatory.

Prolonged use may result in elevated intraocular pressure (IOP), glaucoma, damage to the optic nerve, defects in visual acuity and fields of vision, posterior subcapsular cataract formation, and delayed wound healing; or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissue. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with use of topical steroids.

Acute untreated infection of the eye may be masked or activity enhanced by presence of steroid medication.

Safety and effectiveness have not been demonstrated in children of the age group two years or below.

The preservative in FML®, benzalkonium chloride, may be absorbed by, and cause discolouration of soft contact lenses. Patients wearing soft contact lenses should be instructed to remove contact lenses prior to administration of the solution and wait at least 15 minutes

after instilling FML® before reinserting soft contact lenses.

As fungal infections of the cornea are particularly prone to develop coincidentally with long term local steroid applications, fungus invasion must be suspected in any persistent corneal ulceration where a steroid has been or is in use. Fungal cultures should be taken when appropriate.

FML®, containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface. The use of the bottle by more than one person may spread infection. Keep bottle tightly closed when not in use.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Effects on ability to drive and use machines
Transient blurred vision may occur at instillation. The patient should wait until the vision clears before driving or using machinery.

INTERACTIONS
Although the systemic exposure is expected to be low with topical ophthalmic corticosteriod administration, co-treatment with CYP3A inhibitors may increase the risk of systemic corticosteroid-related side effects.

PREGNANCY AND LACTATION
The safe use of FML® has not been established in humans during pregnancy. Administration of corticosteroids to pregnant animals has been associated with abnormalities of foetal development. FML® has been shown to be embryocidal, foetotoxic, and teratogenic in rabbits when administered by ocular instillation.

It is not known whether topical ophthalmic administration of FML® could result in sufficient

systemic absorption to produce detectable quantities in human breast milk, therefore, FML® is not recommended for breastfeeding women.

DOSAGE AND DIRECTIONS FOR USE

1 to 2 drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

Shake well before use.

Apply the eye drops in the following way:

1.  Tilt your head back and look upward.	2.  Gently pull the lower eyelid down until there is a small pocket.	3.  Squeeze the upturned dropper bottle to release a drop into your eye.	4.  Release the lower lid and close your eye for 30 seconds.

SIDE EFFECTS

Although systemic effects are uncommon, there have been reports of systemic hypercorticoidism after the use of topical steroids, such as FML®.

Post-marketing experience

The following side effects have been identified during post-marketing use of FML®. Because post-marketing reporting is voluntary and from a population of uncertain size, it is not possible to reliably estimate the frequency of these reactions:

Eye disorders

Intraocular pressure increased.

Eye irritation, conjunctival/ocular hyperaemia, eye pain, visual disturbance, foreign body sensation, eyelid oedema, blurred vision, eye discharge, eye pruritus, lacrimation increased, eye oedema / eye swelling, mydriasis, cataract (including subcapsular), ulcerative keratitis, ocular infection (including bacterial, fungal, and viral infections), visual field defect, punctate

keratitis.

Increased intraocular pressure with optic nerve damage, including glaucoma, resulting in decrease of visual acuity or field defects.

Immune system disorders
Hypersensitivity

Nervous system disorders
Dysgeusia

Skin and subcutaneous tissue disorders
Rash

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.
Healthcare professionals, patients and caregivers are also asked to report any suspected adverse reaction to AbbVie (Pty) Ltd via this e-mail address: MEAPV@abbvie.com

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Refer to 'Side Effects and Special Precautions' listed above. Administer symptomatic treatment, if necessary. If accidentally ingested, drink fluids to dilute.

IDENTIFICATION
A white, microfine suspension.

PRESENTATION
FML® Sterile Eye Suspension is supplied in sterile dropper bottles containing 5 ml suspension.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Do not freeze. Store in an upright position. Do not use for longer than

30 days after opening. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

J/15.2/327

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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