Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

FML 0.1% w/v Eye Drops Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each millilitre contains 1 mg Fluorometholone (0.1% w/v).

Excipients with known effect:
0.046 mg Benzalkonium chloride per mL
1.91 mg of Phosphates per mL

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension

A white, microfine suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

FML is indicated for corticosteroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

4.2 Posology and method of administration

Posology

Paediatric population
The safety and efficacy in children aged 2 years or less has not been established.
No data are available.

Elderly population
No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Method of administration:
FML is for topical ophthalmic use only. Shake FML suspension well before use.

Topically as drops into the conjunctival sac.

1-2 drops instilled into the conjunctival sac 2-4 times daily. During the first 24 to 48 hours of treatment, the dose may be safely increased to 2 drops at one hour intervals.

The treatment should not be withdrawn too early.

In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications (see section 4.4).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

FML is contraindicated in active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, as well as mycobacterial and untreated bacterial infection of the eye and fungal diseases of ocular structures.

4.4 Special warnings and precautions for use

Eye drops containing corticosteroids should not be used for longer than a week except under an eye specialist's careful surveillance combined with regular measurement of intraocular pressure.

Prolonged use of corticosteroids may result in elevated intraocular pressure (IOP) with possible development of glaucoma and infrequent damage to the optic nerve, defects in visual acuity and fields of vision, posterior subcapsular cataract formation, and delayed wound healing. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

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

Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Use of a corticosteroid medication in the treatment of the patients with a history of herpes simplex keratitis requires great caution. Frequent slit lamp microscopy is recommended, in severe cases once a day.

To prevent eye injury or contamination, care should be taken to avoid touching the applicator tip to the eye or to any other surface. The use of the bottle by more than one person may spread infection.

This medicine contains 0.046mg Benzalkonium chloride in each ml. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Avoid contact with soft contact lenses. Remove contact lenses before FML is used and wait for at least 15 minutes before reinsertion.

This medicine contains 1.91 mg phosphates in each ml (refer to section 4.8)

Concomitant ocular medication should be administered 5 minutes prior to the instillation of FML.

Visual disturbance
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, the patient should be considered for referral to an ophthalmologist for evaluation of 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.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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

There are no or limited amount of data from the use of fluorometholone in pregnant women.
Studies in animals have shown reproductive toxicity.
FML is not recommended during pregnancy.

Breast-feeding
It is unknown whether fluorometholone/metabolites are excreted in human milk.
FML should not be used during breast-feeding.

4.7 Effects on ability to drive and use machines

FML has no influence on the ability to drive and use machines. However, instillation of any eye drop could result in transient blurring of vision. If this occurs, the patient should wait for the blurring to subside before driving or operating machinery.

4.8 Undesirable effects

Class effects:
Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticoidism after use of topical steroids.

The following undesirable effects have been reported since FML was marketed.

Adverse reactions are categorized by frequency as follows: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000), not known (frequency cannot be estimated from the available data).

Table 1: Adverse reactions

System Organ Class	**Very common (≥1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to < 1/100)**	**Not Known (cannot be estimated from the available data)**
Immune system disorders				Hypersensitivity
Eye disorders		Intraocular pressure increased		Eye irritation, conjunctival/ocular hyperaemia, eye pain, visual disturbance, foreign body sensation in eyes, eyelid oedema, eyelid ptosis, blurred vision*, eye discharge, eye pruritis, 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.
Gastrointestinal disorders				Dysgeusia
Skin and subcutaneous tissue disorders				Rash

*See section 4.4 for further information

Adverse reactions reported in phosphate containing eye drops
Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

Overdosage by the topical ophthalmic route will not ordinarily cause acute problems.

If accidental overdosage occurs in the eye, the eye should be flushed with water or normal saline. If accidentally ingested, the patient should drink fluids to dilute.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, plain
ATC code: S01BA07

Fluorometholone is a synthetic corticosteroid (glucocorticoid), a derivative of desoxyprednisolone. It is a member of the group of universally known steroids used for the treatment of eye inflammation.

Glucocorticoids bind to cytoplasmic receptors and control the synthesis of infection mediators thus damping inflammatory reactions (swelling, fibrin deposition, capillary dilatation, phagocyte migration) and also capillary proliferation, collagen deposition and scarring.

Although topical corticosteroid treatment often increases intraocular pressure both in normal eyes and in the eyes of a patient with increased intraocular pressure, fluorometholone increases intraocular pressure less than, for example, dexamethasone. A study showed that fluorometholone after six weeks' treatment increased intraocular pressure statistically significantly less than dexamethasone (mean change dexamethasone: 9 mmHg, mean change fluorometholone: 3 mmHg).

5.2 Pharmacokinetic properties

When tritium-labelled 0.1 % fluorometholone suspension was administered locally, the peak concentration of the radioactive substance in aqueous humour was achieved 30 minutes after administration. A rapidly forming metabolite occurred at high concentrations both in aqueous humour and corneal extracts, which shows that fluorometholone is metabolised to a certain extent while penetrating the cornea and aqueous humour.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl alcohol
Benzalkonium chloride
Edetate disodium
Sodium chloride
Sodium phosphate dibasic heptahydrate
Sodium phosphate monobasic monohydrate
Polysorbate 80
Sodium hydroxide (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 3 years
Once opened: discard after 28 days

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

A bottle and an applicator tip of low density polyethylene (LDPE). A screw cap of high impact polystyrene (HIPS).

The bottle contains 5ml or 10ml of suspension.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Keep bottle tightly closed when not in use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

AbbVie Limited
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1824/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1978

Date of last renewal: 1st April 2008.

10 DATE OF REVISION OF THE TEXT

June 2025