

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0148/007/002

Case No: 2049159

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Allergan Pharmaceuticals Ireland

Castlebar Road, Westport, Co. Mayo, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

FML Forte Liquifilm 2.5 mg/ml eye drops, suspension

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/04/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

FML Forte Liquifilm 2.5 mg/ml eye drops, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredient</u>	<u>Percent (w/v)</u>	<u>mg/ml</u>
Fluorometholone	0.25	2.50

Excipients:

Benzalkonium chloride 0.05mg/ml

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension

Sterile, white, microfine suspension..

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

FML Forte 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

Adults and children over the age of 2 years only: Instill one drop into the conjunctival sac two to four times daily. In the initial 24 to 48 hours, this dose may be increased to one drop every hour.

Care should be taken not to discontinue therapy prematurely.

4.3 Contraindications

Use in patients who are hypersensitive to corticosteroid preparations.

Use in the presence of fungal, tuberculous, or viral or untreated bacterial infections of the eye.

4.4 Special warnings and precautions for use

Prolonged use may result in glaucoma, corneal thinning and perforation, subcapsular cataract formation, or may facilitate the development of secondary ocular infections.

Steroid medication in the treatment of herpes simplex keratitis (involving the stroma) requires great caution, frequent slit lamp microscopy is mandatory, in severe cases once a day.

Eye drops containing corticosteroids, should not be used for more than one week except under strict ophthalmic supervision with regular checks of intra-ocular pressure.

4.5 Interaction with other medicinal products and other forms of interaction

Corticosteroids may increase the activity of:

Barbiturates
Sedatives and hypnotics
Tricyclic antidepressants

Corticosteroids may decrease the activity of:

Anticholinesterases
Antiviral eye preparations
Salicylates

4.6 Pregnancy and lactation

There are no adequate and well controlled studies in pregnant women. FML Forte should be used during pregnancy only if the potential benefit outweighs the potential risk to the foetus. Use in women breast feeding infants is not recommended.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Glaucoma with optic nerve damage, visual acuity or field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissues, perforation of the globe and delayed wound healing. Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical steroids. Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperaemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids, however, a causal relationship was not determined.

4.9 Overdose

Overdosage will not ordinarily cause acute problems. If accidental overdosage occurs in the eye, flush the eye with water or normal saline. If accidentally ingested, drink fluids to dilute.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fluorometholone, a synthetic corticosteroid, has potent anti-inflammatory activity with a reduced tendency to cause increased intraocular pressure as compared to other topical corticosteroids. Corticosteroids inhibit the inflammatory response to a variety of inciting agents. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, phagocytic activity, capillary proliferation, fibroblast proliferation, deposition of collagen and scar formation associated with inflammation. Inhibition of histidine decarboxylase by corticosteroids inhibits synthesis of histamine from degranulated mast cells. Corticosteroids also decrease prostaglandin synthesis and retard epithelial regeneration. The mechanism of action of corticosteroids has not been entirely established; however, it is believed that corticosteroids block the progression of inflammation by increasing the resistance of cells to cytotoxic breakdown products in the inflammatory zone.

5.2 Pharmacokinetic properties

Refer to 5.1.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl alcohol
Benzalkonium chloride
Disodium edetate
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Sodium phosphate, dibasic, heptahydrate
Polysorbate 80
Sodium hydroxide (for pH-adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 15 months
Opened: 4 weeks

6.4 Special precautions for storage

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

6.5 Nature and contents of container

The product will be marketed in a 5ml and 10ml size. Bottle with dropper applicator, containing a white, microfine sterile ophthalmic suspension. All bottles and tips are made from low density polyethylene. The caps are of polystyrene. A safety seal is placed around the bottle cap to insure integrity of the product.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo

8 MARKETING AUTHORISATION NUMBER

PA 148/7/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th June 1986

Date of last renewal: 16th June 2006

10 DATE OF REVISION OF THE TEXT

November 2006