# AUSTRALIAN PRODUCT INFORMATION – FLAREX (FLUOROMETHOLONE ACETATE) EYE DROPS SUSPENSION

## 1 NAME OF THE MEDICINE

Fluorometholone acetate.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active ingredient in FLAREX EYE DROPS is fluorometholone acetate 1 mg/mL (0.1%).

For the full list of excipients, see Section 6.1 List of excipients.

## 3 PHARMACEUTICAL FORM

Eye drops, suspension. It is a sterile ophthalmic suspension.

## 4 CLINICAL PARTICULARS

### 4.1 THERAPEUTIC INDICATIONS

Fluorometholone Acetate Ophthalmic Suspension is indicated for use in the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the eye.

### 4.2 DOSE AND METHOD OF ADMINISTRATION

Shake well before use.

One to two 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 two drops every two hours. Care should be taken not to discontinue therapy prematurely.

### 4.3 CONTRAINDICATIONS

- Mycobacterial ocular infections
- Herpes simplex keratitis
- Vaccinia, varicella and most other viral diseases of the cornea and conjunctiva
- Tuberculosis of the eye
- Fungal diseases of ocular structures
- Acute untreated infections
- Hypersensitivity to the constituents of this medication.

### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

#### Identified precautions

Employment of steroid medication in the treatment of stromal keratitis or uveitis caused by herpes simplex requires great caution; periodic slit lamp microscopy is essential. Prolonged use may result in ocular hypertension and/or glaucoma, damage to the optic nerve, defects in visual acuity and

visual field, posterior subcapsular cataract formation and/or may aid in the establishment of secondary ocular infections from pathogens due to suppression of host responses.

Acute infections of the eye may be masked or exacerbated by the presence of steroid medications. In those diseases causing thinning of the cornea or sclera, perforation has been known to occur with the chronic use of topical steroids.

It is advisable that the intraocular pressure be checked frequently. This is especially important in paediatric patients, as the risk of corticosteroid induced ocular hypertension may be greater in children and may occur earlier than in adults. FLAREX is not approved for use in paediatric patients. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

Systemic corticosteroid side-effects may occur after intensive or long-term continuous ophthalmic corticosteroid therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (e.g. ritonavir and cobicistat).

Topical ophthalmic corticosteroids may slow corneal wound healing. Topical NSAIDs are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. (See Section 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS).

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 and corticosteroid therapy should be discontinued if fungal infection occurs.

### 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.

### Contact lenses

No contact lenses should be worn under FLAREX treatment. Additionally, this product contains benzalkonium chloride which may cause irritation and is known to discolour soft contact lenses.

### Use in the elderly

No data available.

### Paediatric use

Safety and effectiveness in children have not been established.

It is advisable that the intraocular pressure be checked frequently. This is especially important in paediatric patients, as the risk of corticosteroid induced ocular hypertension may be greater in children and may occur earlier than in adults. FLAREX is not approved for use in paediatric patients

### Effects on laboratory tests

No data available.

## 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems.

Co-treatment with CYP3A4 inhibitors, including ritonavir and cobicistat, may increase systemic exposure resulting in increased risk of systematic 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

### Effects on fertility

There is no data regarding the effects of FLAREX on male or female fertility.

### Use in pregnancy – Pregnancy Category B3

There are no or limited amount of data from the use of FLAREX Eye Drops in pregnant women. FLAREX Eye Drops is not recommended during pregnancy and in women of childbearing potential not using contraception.

Animal reproduction studies have not been conducted with Fluorometholone Acetate Ophthalmic Suspension. Animal studies with corticosteroids have shown reproductive toxicity. It is also not known whether Fluorometholone Acetate Ophthalmic Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, other steroids have been found to be teratogenic. Fluorometholone Acetate Ophthalmic Suspension should be given to a pregnant woman only if clearly needed.

### Use in lactation

It is not known whether this drug and its metabolites are excreted in human milk. Systemic corticosteroids are excreted into human milk. A risk to the suckling child cannot be excluded. Because of the potential for serious adverse reactions in nursing infants from fluorometholone, use only when considered essential by the physician.

## 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until vision clears before driving or using machinery.

## 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Glaucoma with optic nerve damage, visual acuity and field defects, cataract formation, secondary ocular infection following suppression of host response and perforation of the globe may occur.

### Post Marketing Experience

The following adverse reactions have been reported following use of fluorometholone topical ophthalmic preparations. Frequencies cannot be estimated from the available data. Adverse reactions are presented in order of decreasing seriousness.

***Eye Disorders***

Intraocular pressure increased, vision blurred (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE), eye pain, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, lacrimation increased.

***Gastrointestinal Disorders***

Dysgeusia.

### Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

## 4.9 OVERDOSE

An ocular overdose of FLAREX Eye Drops is not likely to be associated with toxicity. Accidental ingestion is also unlikely to be associated with toxicity. Treatment of suspected ingestion should be symptomatic and supportive.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: ophthalmological, anti-inflammatory agents, corticosteroids. ATC code: S01BA07.

### Mechanism of action

Corticosteroids suppress the inflammatory response to a variety of agents.

### Clinical trials

Clinical studies demonstrate that fluorometholone acetate is significantly more efficacious than fluorometholone for the treatment of external ocular inflammation. Corticosteroids cause a rise in intraocular pressure in susceptible individuals. In clinical studies, Fluorometholone Acetate Ophthalmic Suspension was demonstrated to raise intraocular pressure more slowly but ultimately to the same extent as dexamethasone phosphate.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 LIST OF EXCIPIENTS

Each mL contains benzalkonium chloride, sodium biphosphate, tyloxapol, disodium edetate, sodium chloride, hyetellose, hydrochloric acid/sodium hydroxide to adjust pH, purified water.

## 6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

## 6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

## 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

Shake well before use.

## 6.5 NATURE AND CONTENTS OF CONTAINER

As a sterile ophthalmic suspension in 5 mL and 10 mL opaque LDPE bottles.

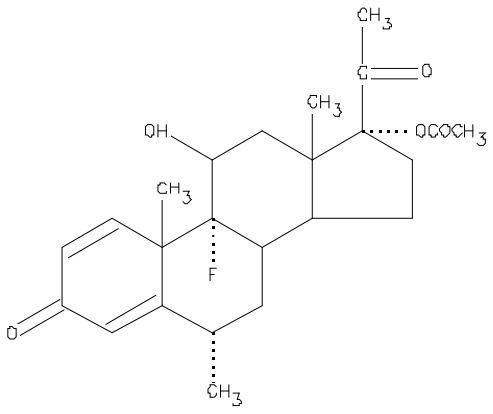
## 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

## 6.7 PHYSICOCHEMICAL PROPERTIES

### Chemical structure

Its chemical name is 9$\alpha$-fluoro-11ß-17$\alpha$ dihydroxy-6$\alpha$-methyl pregna-1, 4-diene-3, 20-dione 17-acetate. The chemical structure of fluorometholone acetate is presented below:



Fluorometholone acetate, a corticosteroid, is a white to creamy white powder with an empirical formula of $C_{24}H_{31}FO_5$ and a molecular weight of 418.5.

### CAS number

426-13-1

## 7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine (Schedule 4)

## 8 SPONSOR

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## 9 DATE OF FIRST APPROVAL

15 October 1991

## 10 DATE OF REVISION

13 November 2023

### SUMMARY TABLE OF CHANGES

| Section Changed | Summary of new information |
|---|---|
| **6.5** | Removed DROP-TAINER™ and included the container, bottle and the container material. |

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