PRODUCT INFORMATION

FLUCON® STERILE OPHTHALMIC SUSPENSION

(Fluorometholone)

DESCRIPTION

A sterile ophthalmic suspension, each mL containing:

Active: fluorometholone 1.0 mg.

Preservative: benzalkonium chloride 0.1 mg.

Inactives: sodium phosphate-monobasic, sodium phosphate-dibasic anhydrous, polysorbate 80, sodium chloride, disodium edetate, polyvinyl alcohol, hypromellose and purified water.

PHARMACOLOGY

Inhibition of the inflammatory response to inciting agents of mechanical, chemical or immunological nature. No generally accepted explanation of the steroid property has been advanced. Adrenocorticosteroids and their derivatives are capable of producing a rise in intraocular pressure. In clinical studies on patients' eyes treated with both dexamethasone and fluorometholone, fluorometholone demonstrated a lower propensity to increase intraocular pressure than did dexamethasone.

INDICATIONS

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

CONTRAINDICATIONS

Acute, untreated bacterial infections.

Herpes simplex keratitis.

Fungal diseases of ocular structures.

Vaccinia, varicella and most other viral diseases of the cornea and conjunctiva.

Tuberculosis of the eye.

Hypersensitivity to the constituents of this medication.

Mycobacterial ocular infections.

PRECAUTIONS

Employment of steroid medication in the treatment of stromal keratitis or uveitis caused by herpes simplex requires great caution; frequent slit lamp microscopy is mandatory. 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. Corticosteroids may reduce resistance to and aid in the establishment of bacterial, viral or fungal secondary ocular infection from pathogens liberated from ocular tissue. In those diseases causing thinning of the cornea, or sclera, perforation has been known to occur with the use of topical steroids. Acute untreated infection may be masked or enhanced by steroid medication.

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 INTERACTIONS WITH OTHER MEDICINES).

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 used or is in use and corticosteroids therapy should be discontinued if fungal infection occurs.

In patients receiving ophthalmic corticosteroid therapy intraocular pressure should be checked regularly. 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. FLUCON 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).

Carcinogenicity, Mutagenicity, Effects on Fertility

There are no data regarding the effects of FLUCON Eye Drops on male or female fertility.

Use in Pregnancy

Category B3

There are no or limited amount of data from the use of FLUCON Eye Drops in pregnant women. Animal studies with corticosteroids have shown reproductive toxicity. FLUCON Eye Drops is not recommended during pregnancy and in women of childbearing potential not using contraception.

Use in Lactation

There is insufficient information on whether fluorometholone and its metabolites from FLUCON Eye Drops 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.

Paediatric Use

In patients receiving ophthalmic corticosteroid therapy intraocular pressure should be checked regularly. 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. FLUCON is not approved for use in paediatric patients.

Contact Lenses

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

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 the vision clears before driving or using machinery.

INTERACTIONS WITH OTHER MEDICINES

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

ADVERSE EFFECTS

Glaucoma with optic nerve damage, visual acuity or field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens liberated from ocular tissue, perforation of the globe.

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, eye pain, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, lacrimation increased.

Gastrointestinal Disorders

Dysgeusia.

DOSAGE AND ADMINISTRATION

One or 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 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

OVERDOSAGE

An ocular overdose of FLUCON 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.

In Australia, contact the Poisons Information Centre on 13 11 26 for advice on management.

PRESENTATION AND STORAGE CONDITIONS

As a sterile suspension in 5 mL plastic DROP-TAINER™ dispensers.

Store at or below 25°C. Do not refrigerate or freeze.

Discard container 4 weeks after opening.

NAME AND ADDRESS OF THE SPONSOR

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113.

POISON SCHEDULE OF THE MEDICINE

Prescription Only Medicine (Schedule 4)

DATE OF FIRST INCLUSION IN THE ARTG

15 October 1991

DATE OF MOST RECENT AMENDMENT

5 July 2017

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