
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.

ACTIONS:

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 purulent bacterial infections

Acute superficial 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.

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.

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 from FLUCON[®] Eye Drops is excreted in 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.

CARCINOGENICITY, MUTAGENICITY, EFFECTS ON FERTILITY

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

INTERACTIONS WITH OTHER MEDICINES

No relevant interactions have been described with FLUCON[®] Eye Drops.

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.

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

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

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 Poisons Information Centre on 13 11 26; in New Zealand call 0800 POISON or 0800 764 766 for advice on management.

PRESENTATION AND STORAGE:

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

Store below 25°C.

Discard container 4 weeks after opening.

NAME AND ADDRESS OF THE SPONSOR

This product is made in Belgium and supplied in Australia by:

ALCON LABORATORIES (Australia) Pty Ltd
25 Frenchs Forest Road East
Frenchs Forest NSW 2086

In New Zealand this product is distributed by:

Alcon New Zealand Limited
c/o Pharmaco (NZ) Limited
4 Fisher Crescent
Mt Wellington Auckland

POISON SCHEDULE OF THE MEDICINE

Prescription Only Medicine (Schedule 4)

Date of most recent amendment: 6 July 2011

[®] Registered Trademark
[™] Trademark