NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Flucon® fluorometholone 0.1% Eye Drops Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Flucon contains 1.0 mg of fluorometholone (0.1% w/v).

Excipient with known effect

Benzalkonium chloride 0.1 mg in 1 mL as a preservative.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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

4.2. Dose and method of 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.

4.3. 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.
- Mycobacterial ocular infections.
- Hypersensitivity to fluorometholone and the other constituents of this medication. (See Section 6.1. List of excipients).

4.4. Special warnings and precautions for use

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 area also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. (See 4.5. Interactions with other medicinal products and other forms of interactions.).

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.

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).

The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).

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.

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.

4.5 Interactions with other medicinal products 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

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 are not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

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.

Fertility

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

4.7 Effects on ability to drive or 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.

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 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 (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 of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting.

4.9 Overdose

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: corticosteroids, plain, ATC code: S01BA07.

Mechanism of action

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.

Pharmacodynamic effects

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.

5.2 Pharmacokinetic properties

No information is available.

5.3 Preclinical safety data

No information is available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride as a preservative

Sodium phosphate-monobasic

Sodium phosphate-dibasic anhydrous

Polysorbate 80

Sodium chloride

Disodium edetate

Polyvinyl alcohol

Hypromellose

Purified water.

6.2 Incompatibilities

Not known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25° C.
Do not refrigerate.
Do not freeze.
Discard container 4 weeks after opening.

6.5 Nature and contents of container

5ml Drop-Tainer™ bottle and dropper.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription Only Medicine.

8. SPONSOR

Novartis New Zealand Limited

109 Carlton Gore Road

Newmarket

Auckland 1023.

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New Zealand.

Free Phone: 0800 354 335.

9. DATE OF FIRST APPROVAL

18 November 1982.

10. DATE OF REVISION OF THE TEXT

30 July 2018

Summary Table of Changes

4.4	Addition of Visual disturbance as recommended by Medsafe letter dated 10th May 2018.

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