1. NAME OF THE MEDICINAL PRODUCT

FLUCON® 0.1% sterile ophthalmic suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of suspension contains 1 mg fluorometholone.
Preservative: 1 ml of suspension contains 0.1 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sterile ophthalmic suspension.
White to off-white suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FLUCON ophthalmic suspension contains fluorometholone, a corticosteroid.

FLUCON ophthalmic suspension is indicated for the treatment of corticosteroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

4.2 Posology and method of administration

Posology
1 to 2 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.

Use in patients with hepatic or renal impairment
The safety and efficacy of FLUCON ophthalmic suspension in patients with hepatic or renal impairment have not been established.

Method of administration
For ocular use.
Shake well before use.

After cap is removed, if tamper evident snap collar is loose, remove before using product.

To prevent contamination of the dropper tip and suspension, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use.

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.

If more than one topical ophthalmic product is being used, the products must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Acute, untreated bacterial infections.
- Herpes simplex keratitis.
- Vaccinia, varicella and other viral infection of cornea or conjunctiva.
- Fungal diseases of ocular structures.
- Mycobacterial ocular infections.

4.4 Special warnings and precautions for use

- Employment of steroid medication in the treatment of stromal herpes simplex infection requires great caution. Frequent slit lamp microscopy is mandatory.
- Prolonged use of topical ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, reduced visual acuity and visual field defects, and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and 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.
- 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).
- Corticosteroids may reduce resistance to and aid in the establishment of bacterial, fungal or viral infections and mask the clinical signs of infection.
- Fungal infection should be suspected in patients with persistent corneal ulceration who have been or are receiving these drugs, and corticosteroids therapy should be discontinued if fungal infection occurs. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications.
- 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 corticosteroids may increase the potential for healing problems (see section 4.5).
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.
- The wearing of contact lenses is discouraged during treatment of an ocular inflammation. FLUCON ophthalmic suspension contains benzalkonium chloride which may cause irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. In case patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of FLUCON ophthalmic suspension and wait at least 15 minutes before reinsertion.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of FLUCON ophthalmic suspension 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
There are no or limited amount of data from the use of FLUCON ophthalmic suspension in pregnant women. Studies in animals with corticosteroids have shown reproductive toxicity.

FLUCON ophthalmic suspension is not recommended during pregnancy.

Breast-feeding
It is unknown whether fluorometholone or its metabolites are excreted in human milk following topical ocular administration. Systemic corticosteroids are excreted into human milk. A risk to the suckling child cannot be excluded.

Breast-feeding should be discontinued during treatment with FLUCON ophthalmic suspension.

Fertility
There are no data regarding the effects of FLUCON ophthalmic suspension on male or female fertility.

4.7 Effects on ability to drive and use machines

FLUCON ophthalmic suspension has no or negligible influence on the 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 after instillation, the patient must wait until the vision clears before driving or using machinery.

4.8 Undesirable effects

Tabulated list of adverse reactions
The following adverse reactions have been identified from post-marketing surveillance following administration of FLUCON ophthalmic suspension. Frequencies cannot be estimated from the available data. Within each System Organ Class adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	Adverse reactions
Eye disorders	intraocular pressure increased, eye pain, eye irritation, ocular discomfort, foreign body sensation in eyes, vision blurred, ocular hyperaemia, lacrimation increased
Gastrointestinal disorders	dysgeusia

Description of selected adverse reactions
- Prolonged use of topical ophthalmic corticosteroids may result in increased intraocular pressure with damage to the optic nerve, reduced visual acuity and visual field defects, posterior subcapsular cataract formation and delayed wound healing (see section 4.4).
- The development of secondary infections has occurred after the use of corticosteroids (see section 4.4).
- In diseases causing thinning of the cornea or sclera there is a higher risk for perforation especially after longer treatment (see section 4.4.).

4.9 Overdose

An ocular overdose of FLUCON ophthalmic suspension may be flushed from the eye(s) with lukewarm water.

An ocular overdose of FLUCON ophthalmic suspension is not likely to be associated with toxicity. Accidental ingestion is also unlikely to be associated with toxicity.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

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

5.2 Pharmacokinetic properties

The corticosteroids are absorbed in the aqueous humour, the cornea, the iris and the ciliary body. Systemic resorption may occur, but is only significant at high doses or during prolonged treatment in children.

5.3 Preclinical safety data

Non-clinical studies of repeated dose topical ocular administration did not show any special hazard for short term use of this product in humans.

Carcinogenesis, mutagenesis, impairment of fertility: No studies have been conducted in animals or in humans to evaluate the possibility of these effects with fluorometholone.

Adverse reactions seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows: Fluorometholone has been shown to be embryocidal and teratogenic in rabbits when administered at low multiples of the human ocular dose. Fluorometholone was applied ocularly to rabbits daily on days 6-18 of gestation, and dose-related foetal loss and foetal abnormalities including cleft palate, deformed rib cage, anomalous limbs and neural abnormalities such as encephalocele, craniorachischisis and spina bifida were observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, polysorbate 80, sodium chloride, benzalkonium chloride, disodium edetate, polyvinyl alcohol, hypromellose, sodium hydroxide and/or hydrochloric acid (to adjust pH), purified water.

6.2 Incompatibilities

Not applicable.

6.3 Special precautions for storage

Store upright. Do not store above 25°C. Do not refrigerate or freeze.
Do not use this medicine after the expiry date which is stated on the packaging.
Discard 4 weeks after first opening.
Keep this medicine out of the sight and reach of children.

6.4 Nature and contents of container

Plastic DROP-TAINER® dispenser containing 5 ml.

6.5 Special precautions for disposal

No special requirements.

Manufactured by:

ALCON-COUVREUR
B-2870 Puurs (Belgium) for Novartis Pharma AG, Basel, Switzerland

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