SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

Fluroton Ophthalmic Suspension

(Fluorometholone Acetate Ophthalmic Suspension, 0.1% w/v)

2. Qualitative and Quantitative Composition

Each ml contains Fluorometholone Acetate USP 1 mg. For a full list of excipients, see section 6.1.

3. Pharmaceutical Form

Ophthalmic Suspension

An almost white suspension

4. Clinical Particulars

4.1 Therapeutic indications

Fluroton 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 Posology and method of administration

Shake well before use.

One drop 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 hourly. 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. Fluroton 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 present 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 Fluorometholone Acetate Ophthalmic Suspension treatment.

Use in the elderly

No data available.

Paediatric Use

Safety and effectiveness in children below the age of 2 years 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. Fluorometholone Acetate Ophthalmic Suspension is not approved for use in paediatric patients

Effects on Laboratory Tests

No data available.

4.5 Interaction With Other Medicinal Products

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 Fluorometholone Acetate Ophthalmic Suspension on male or female fertility.

Use in Pregnancy – Pregnancy Category B3

There are no or limited amount of data from the use of Fluorometholone Acetate Ophthalmic Suspension in pregnant women. Fluorometholone Acetate Ophthalmic Suspension 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 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, eye pain, ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, lacrimation increased.

Gastrointestinal Disorders

Dysgeusia.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents.

4.9 Overdose

An ocular overdose of Fluorometholone Acetate Ophthalmic Suspension 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.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

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

Mechanism of action

Fluorometholone is thought to act by the induction of phospholipase A2 inhibitory proteins which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid.

5.2 Pharmacokinetic Properties

When tritium-labelled 0.1 % fluorometholone suspension was administered locally, the peak concentration of the radioactive substance in aqueous humour was achieved 30 minutes after administration. A rapidly forming metabolite occurred at high concentrations both in aqueous humour and corneal extracts, which shows that fluorometholone is metabolised to a certain extent while penetrating the cornea and aqueous humour.

5.3 Preclinical safety data

No data available

6. Pharmaceutical Particulars

6.1 List of excipients

Hydroxyethyl Cellulsoe, Sodium Chloride, Disodium Edetate Sodium Dihydrogen Phosphate Dihydrate, Tyloxapol, Sodium Perborate, Sodium Hydroxide, Hydrochloric Acid and Water for Injections.

6.2 Incompatibilities

Not Applicable.

6.3 Shelf Life

2 years.

After first opening: use within 30 days.

6.4 Special Precautions for Storage

Store below 30°C, Protect from light, Protect from freezing, Keep out of reach of children.

6.5 Nature and Contents of Container

Low Density Polyethylene (LDPE) white opaque dropper bottle with a LDPE white opaque dropper tip and High Density Polyethylene (HDPE) white opaque closure.

6.6 Special Precautions for Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site

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8. Marketing Authorization Number

CTD13418.

9. Date of First Registration/Renewal of the Registration

14/06/2026

10. Date of Revision of the Text

14/06/2026