Anti-inflammatory corticosteroid

Flumetholon® ophthalmic suspension

(Fluorometholone 0.1%)

Flumetholon® is an aqueous ophthalmic suspension which contains 0.1% fluorometholone (9-Fluoro-11β,17-dihydroxy-6α-methylpregna-1,4-diene-3,20-dione), an anti-inflammatory syntetic corticosteroid. Flumetholon® is effective for treating ocular inflammatory diseases.

[Description]

Brand name	Flumetholon®
Active ingredient	Fluorometholone
Content per mL	1 mg
Inactive ingredient	Disodium edetate hydrate, benzalkonium chloride, polysorbate 80 and methylcellulose
pH	6.8 – 7.8
Osmolar ratio	0.9 – 1.1
Description	Sterile aqueous ophthalmic suspension which produces white turbidity on shaking

[Indications]

Inflammatory diseases in the outer ocular area and in the anterior segment of the eye: blepharitis, conjunctivitis, keratitis, scleritis, episcleritis, iritis, iridocyclitis, uveitis, postoperative inflammation, etc.

[Dosage and Administration]

Shake well before use. Usually, instill 1-2 drops a time to the eye 2-4 times daily. The dosage may be adjusted according to the patient's age and symptoms.

[Pharmacology]

Anti-inflammatory effect

Fluorometholone ophthalmic suspension exerts an anti-inflammatory effect comparable to that of a dexamethasone ophthalmic preparation of the same concentration on experimental uveitis induced by ferritin or bovine serum protein in rabbits.

[Precautions]

[Contraindications] (Flumetholon® is contraindicated in the following patients)
Patients with a history of hypersensitivity to any ingredients of this product.

[Relative Contraindications] (As a general rule, Flumetholon® is contraindicated in the following patients. If the use of Flumetholon® is considered essential, it should be administered with care)

1) Patients with corneal erosion or corneal ulcer. [Flumetholon® may aggravate these diseases or cause corneal perforation]
2) Patients with viral keratoconjunctivitis, tuberculous eye disease, fungal or suppurative eye disease. [Flumetholon® may aggravate these diseases or cause corneal perforation]

1. Adverse Reactions

Adverse reactions to this drug were reported in 25 of 10,343 patients evaluated before and after approval (0.24%). The major adverse reactions were ocular hypertension in 13 patients (0.13%), eye irritation /conjunctival hyperaemia in 5 patients (0.05%), and eye discharge in 4 patients (0.04%).

1) Clinically significant adverse reactions (rarely: < 0.1%, occasionally: 5%> ≥ 0.1%, and no specific designation: ≥ 5% or incidence unknown).

(1) **Glaucoma**: Ocular hypertension and glaucoma may occur occasionally after several weeks of repeated treatment with this drug. The intraocular pressure should be monitored periodically during treatment.

(2) **Corneal herpes, Keratomycosis, *Pseudomonas aeruginosa* infection:** Corneal herpes, keratomycosis, *Pseudomonas aeruginosa*, etc. may be induced by this drug. If such symptoms are observed, appropriate measures should be taken.

(3) **Perforation:** Corneal perforation may occur if this drug is given to patients with corneal herpes, corneal ulcer or trauma, etc.

(4) **Posterior subcapsular cataract:** Posterior subcapsular cataract may occur with the long-term use of this drug.

2) Other adverse reactions

If the following adverse reactions are observed, appropriate measures such as discontinuing administration should be taken.

Type / Incidence	Incidence unknown
Hypersensitivity	Blepharitis, dermatitis, eyelid, rash
Ophthalmic	Irritation, conjunctival hyperaemia, corneal deposits
Pituitary-adrenocortical system (if used in the long-term)	Pituitary-adrenocortical system suppression
Others	Delay of wound healing

2. Use In The Elderly

Because physiological function is generally reduced in the elderly, caution should be exercised when this drug is used in elderly patients.

3. Use During Pregnancy, Delivery or Lactation

Long-term or frequent use of this product should be avoided in pregnant women or women who may possibly be pregnant. [The safety of this product during pregnancy has not been established].

4. Pediatric Use

This product should be administered with care especially to infants under 2 years old. [The safety of this drug in infants and children has not been established].

5. Precautions Concerning Use

1) Route of administration: Ophthalmic use only.
2) At the time of administration: Instruct the patient to be careful not to touch the tip of the bottle to the eye directly in order to avoid the contamination of the drug.
3) Since particles in the suspension may not disperse depending on storage conditions even after well shaking, store the product in an upright position.

"Special warning and special precaution for use:
Benzalkonium chloride, which is commonly used as a preservative in ophthalmic product, has been reported to have cytotoxicity. Since this drug contains benzalkonium chloride, close monitoring is required with frequent or prolonged use in dry eye patients, or in conditions where the cornea is compromised.
Contact lenses
The preservative in this drug, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses should be instructed to wait at least fifteen minutes after instilling this drug before they insert contact lenses."

[Storage]

Store below 30°C, in an upright position. Use within 1 month after opening.

[How Supplied]

Box, plastic bottle @ 5 ml

HARUS DENGAN RESEP DOKTER

Reg. No. DKI2167601246A1

Manufactured by:
Santen Pharmaceutical Co., Ltd.
Shiga Plant: 348-3, Aza-suwa, Oaza-shide, Taga-cho, Inukami-gun, Shiga, Japan

Imported, secondary packaged and marketed by

meiji

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