1. NAME OF THE MEDICINAL PRODUCT
FLAREX 1 mg/ml, eye drops, suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Fluorometholone acetate 1.0 mg/ml.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM
Eye drops, suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Steroid responsive allergic and other inflammatory conditions of the palpebral and bulbar conjuctiva cornea and anterior sequal of the eye.

4.2 Posology and method of administration
Shake well before use.
Adults: 1 to 2 drops in the conjunctival sac 4 times daily. During the initial 48 hours the dosage may be safely increased to 2 drops every 2 hours. If there is no improvement after 2 weeks, consult the physician. Care should be taken not to discontinue therapy prematurely.
Children: FLAREX is usually not recommended for pediatric use since its safety and effectiveness have not been established.
Elderlv: There are no special precautions to be followed.
if used in patients with glaucoma, treatment should be limited to 2 weeks, unless longer treatment is justified (see 4.3 Contraindications and 4.4 Special warnings and special precautions for use).

4.3 Contraindications
Hypersensitivity to fluorometholone acetate or to one of the excipients; herpetic keratitis (dendritic keratitis), vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva; tuberculous lesions; fungal diseases of the eye structures; and untreated bacterial infections of the eye. Corticosteroids should not be used with infections or injuries limited to the superficial corneal epithelium.

4.4 Special warnings and special precautions for use
Not for injection.
The extensive and/or prolonged use of ophthalmic corticosteroids increases the risk of ocular complications and could cause systemic side effects. If the inflammatory condition does not respond within a reasonable period during the course of the therapy, other forms of therapy should be instituted to reduce these risks.
Topical application of corticosteroids may be accompanied by a decrease in the urinary secretion of cortisol as well as a decrease in plasma cortisol concentration.

Corticosteroids have been associated with a decreased rate of growth in children, especially with high-dose or long-term treatment.
Prolonged use of ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defect in visual acuity and fields of vision, and posterior subcapsular cataract formation. The risk of corticosteroid-induced raised intraocular pressure is increased for a patient with a family or personal history of glaucoma. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Patients with glaucoma should be monitored weekly.
Corticosteroids may mask infection or enhance existing infection. Prolonged use may suppress the immune response and thus increase the hazard of secondary ocular infections. Appropriate antibiotic therapy should be instituted for concurrent bacterial infections. The possibility of persistent fungal infections of the comea should be considered after prolonged corticosteroid administration.
Ocular herpes simplex has occurred in patients under systemic or local corticosteroid therapy for other conditions. The use of corticosteroid medication in the treatment of herpes simplex other than epithelial herpes simplex keratitis, in which it is contraindicated, requires great caution; periodic split-lamp microscopy is essential.
In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.
The treatment should not be discontinued prematurely as a flare-up of the inflammatory condition may occur with the sudden interruption of high doses of corticosteroids.
The wearing of contact lenses (hard or soft) is discouraged dwing treatment with topical ophthalmic corticosteroids. The preservative benzalkonium chloride can be absorbed by soft contact lenses and may discolor lenses or cause eye irritation.
FLAREX should not be instilled while wearing contact lenses.
After application of the eye drops following measures are useful to reduce systemic resorption:
- Keep the eyelid closed for 2 minutes.
- Close the lacrimal duct with the finger for 2 minutes.

4.5 interaction with other medicinal products and other forms of interaction
During use of eye drops which are administered to dilate pupils (atropine and other anticholinergic substances), which may cause elevation of intraocular pressure, an additive elevation of intraocular pressure may occur if FLAREX is used concomitantly. Ophthalmic corticosteroids may cause an increase in intraocular pressure, reducing the efficacy of glaucoma medications.
If supplementary eye preparations are to be used, one should wait about 15 minutes between 2 applications.

4.6 Pregnancy and lactation
Pregnancy
Fluorometholone teratogenicity and embryotoxicity has been established with rabbits. It is not known whether FLAREX can cause fetal harm when administered to a pregnant woman or whether it can affect reproduction capacity. However, other corticoids have been found teratogenic.

FLAREX should be administered to a pregnant woman only when clearly needed.
Lactation

It is not known whether this drug is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised when FLAREX is administered to a nursing woman.

4.7 Effects on ability to drive and use machines
As with any eye drop, temporarily 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
The following adverse events have been reported following use of this or similar ophthalmic preparations:

Eye disorders
Uncommon (≥ 0.1% <1%): eye irritation, ocular hyperemia.
Rare (≥ 0.01% < 0.1%): eye oedema, eye pruritus, visual acuity reduced, subcapsular cataract, glaucoma, visual field defect, mydriasis, eyelid ptosis.

General disorders and administration site conditions
Rare (≥0.01% < 0.1%): impaired healing.

Immune system disorders
Rare (≥0.01% < 0.1%): hypersensitivity.
Infections and infestations
Rare (≥0.01% < 0.1%): eye infection (exacerbation or secondary).
Injury, poisoning and procedural complications
Very Rare (< 0.01%): corneal perforation.

Investigations
Uncommon (≥0.1% <1%): increased intraocular pressure.

4.9 Overdose
A topical overdose is not likely to be associated with toxicity. A topical overdose of FLAREX
can be flushed from the eye(s) with tepid water. Treatment of an accidental oral ingestion is
symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: anti-inflammatory agents, corticosteroids.
ATC code: S 01 BA 07
Fluorometholone acetate is a synthetic steroid with strong anti-inflammatory properties.
Clinical studies have demonstrated that fluorometholone acetate is significantly more efficacious in the treatment of external ocular inflammation than fluorometholone.
Corticosteroids may cause a rise in intraocular pressure in some susceptible individuals. In a study using persons sensible to steroids, FLAREX ophthalmic

suspension demonstrated a significantly longer average time to produce a rise in intraocular pressure than did dexamethasone phosphate.

5.2 Pharmacokinetic properties
Results from animal studies have demonstrated that fluorometholone acetate, applied in the
eye, is well absorbed and distributed in the cornea and the aqueous humor.

5.3 Preclinical safety data
No data provided.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium chloride 0.1 mg — disodium edetate — sodium dihydrogen phosphate monohydrate — tyloxapol — sodium chloride — hydroxyethylcellulose — hydrochloric acid and/or sodium hydroxide — purified water to 1 ml.

6.2 Incompatibilities
None known.

6.3 Shelf life
Unopened : 36 months.
See expiry date on the package next to the sign "Exp." (month/year).
Discard 28 days after first opening of the bottle.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
Droptainer of 5 ml.

6.6 Instructions for use and handling and disposal
No special requirements.

Manufacturer
Alcon Couvreur N.V. Belgium

License Holder
Lapidot Medical Import and Marketing LTD