SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product:
FLUOMOLINE (Fluorometholone and Tetrahydrozoline Hydrochloride Ophthalmic Suspension)

2. Qualitative and Quantitative Composition:
Composition:

Fluorometholone	USP	0.1 % w/v
Tetrahydrozoline Hydrochloride	USP	0.025 % w/v
Benzalkonium Chloride Solution	USP	
Eq. to Benzalkonium Chloride (as preservative)		0.01% w/v
Aqueous base	qs	

3. Pharmaceutical form:
Ophthalmic Suspension.

4. Clinical particulars:
4.1 Therapeutic indications:
• Acute and chronic allergic non-infectious conjunctivitis and keratitis with severe swelling and intravascular injection.

• Non-infectious inflammation of the anterior segment of the eye (including anterior uveitis, episcleritis and scleritis)

• Post-operative irritative conditions after strabismus; cataract & glaucoma surgery with supplementary antimicrobial therapy.

4.2 Posology and method of administration:
Adults: Instill one (1) drop 2-3 times daily into the conjunctival sac. In the first 24-48 hours, the dose may be increased to 1 drop hourly for adults. Caution should be exercised in the case of reactive hyperaemia.

Children (above 2 years): No specific studies have been performed. Due to possible systemic adverse effects, Fluomoline should be used with caution in children.

Overdosage

Overdose through local administration is not known. An acute overdose with tetryzoline may cause the following symptoms: Mydriasis, cyanosis, high temperature, cardiac disorders and inhibition of central nervous functions. In case of accidental oral intake, specific measures should be taken: charcoal tablets, irrigation of the stomach, artificial respiration with 02, antihypertensive

phentolamine (5 mg in a saline solution I.V.) and if necessary anti-pyretics and anticonvulsive therapy.

4.3 Contraindications:

This medication is contraindicated in following cases-

• Fungal infection of the cornea & conjunctiva or keratitis.

• Ulcerous processes of the cornea

• Hypersensitivity to any ingredients of this formulation.

•Injuries and ulcerative processes of the cornea, especially infections caused by virus, bacteria and fungus (e.g. herpes simplex, vaccinia, purulent untreated infections, tuberculosis).

• Glaucoma In diseases associated with stromal damage of the cornea or sclera, the topical application of corticosteroids may cause perforation of these tissues.

• Dry eyes, especially kerato-conjunctivitis sicca (Sjogren's syndrome).

• Children under 2 years.

4.4 Special warnings and precautions for use:

The preparation should only be administered after a careful risk/benefit evaluation in each individual patient in case of:

Severe blood circulatory diseases (e.g. coronary heart condition, hypertonia, phaeochromocytoma);

Metabolic disturbances (e.g., hyperthyroidism, diabetes); patients, who are under treatment with monoamine oxidase inhibitors (MAOIs) and other potentially hypertensive drugs;

History of cataract, herpes simplex infection, or rhinitis sicca.

After discontinuation of the preparation, reactive hyperaemia is possible. This preparation is not meant for prolonged use. In case of long-term treatment (more than 2 or 3 days) patients should be regularly examined with regard to intraocular pressure, systemic adverse reactions and secondary infections.

Fungus invasion must be suspected in any persistent corneal ulceration.

Fluomoline could mask, activate or aggravate an infection in the eye. Hypersensitivity reactions against ingredients of Fluomoline can be masked.

For patients wearing contact lenses: In the case of eye infections the lenses should not be worn.

4.5 Interaction with other medicinal products and other forms of interaction:

Tetrahydrozoline may interact with antidepressant drugs which inhibits Mono Amino Oxidase (MAO) Enzyme such as Isocarboxazid, phenelzine and its sulphate derivative, Toloxatone, Tranylcypromine and its sulphate derivative etc.

4.6 Fertility, pregnancy and lactation:

No adequate and well-controlled study of Fluomoline has been established during pregnancy & breast feeding. Therefore, this combination should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

4.7 Effects on ability to drive and use machines:

After application, Fluomoline eye drops may temporarily influence the visual acuity. Thus, patients driving vehicles or operating machinery should be alerted of the possibility of reduced reaction time and thereby impaired capability to drive motor vehicles and to operate machinery.

4.8 Undesirable effects:

• A slight burning sensation may occur for a short time after application of the eye drops.

• Prolonged use may give rise to reactive hyperaemia (rebound effect). In rare cases allergic reactions in the form of palpebral eczema, keratitis punctata or periocular dermatitis have been reported.

• Generally, after local application of steroids the following adverse reactions may occur: Secondary infections and increased susceptibility to infections (especially mycosis/herpes simplex), delayed wound healing, mydriasis and very rarely ptosis/exophthalmus, trophic corneal damage (may already occur after 1 week of treatment).

The following effects have been reported after long-term treatment with steroids: Increase in intraocular pressure (the pressure should be controlled periodically), posterior subcapsular cataracts, and enhancement of the development of secondary fungal infection, corneal melting and perforation of the globe, systemic adverse reaction (especially with children and geriatric patients).

Tetrahydrozoline may cause irritation of the conjunctiva, dry mucous membrane and in rare cases mydriasis. In spite of the low doses for topical application, systemic sympathomimetic adverse reactions of the vasoconstrictors are not impossible: Palpitations, arrhythmia, angina, hypertension, occipital headaches, paleness, central excitation, tremor, sweating.

After application, Fluomoline eye drops may temporarily influence the visual acuity. Thus, patients driving vehicles or operating machinery should be alerted to the possibility of reduced reaction time and thereby impaired capability to drive motor vehicles and to operate machinery.

4.9 Overdose:
Information not available.

5. Pharmacological properties:
5.1 Pharmacodynamic properties:

• The anti-inflammatory action of fluorometholone is at least 40 times stronger than that of hydrocortisone. Like all anti-inflammatory glucocorticoids, fluorometholone inhibits the phospholipase A2 (PLA2), the first step in prostaglandin synthesis. Fluorometholone also inhibits the chemotactic infiltration of neutrophiles into the focus of inflammation.
• In contrast to other topical glucocorticoids, fluorometholone has an anti-inflammatory action without significantly influencing the intraocular pressure.
• In comparison with other corticosteroids, fluorometholone is more rapidly degraded in the tissue and therefore has less effect on the intraocular pressure.
• The immunosuppressive action of fluorometholone is less pronounced than that of dexamethasone.
• Tetrahydrozoline is an alpha-sympathomimetic, which causes local vasoconstriction. The vasoconstrictive action of tetryzoline sets in rapidly and alleviates swelling, hyperaemia and irritation of the conjunctiva.
• Fluomoline contains the viscosity enhancing excipient Hydroxypropylmethyl-cellulose. It increases the effect of the product by prolonging the retention time on the cornea.

5.2 Pharmacokinetic properties:
5.3 Preclinical safety data:
Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose ocular toxicity and repeated dose systemic toxicity.

6. Pharmaceutical particulars:
6.1 List of excipients:
Benzalkonium Chloride solution USP eq. to
Benzalkonium Chloride
Polyvinyl Alcohol
Disodium EDTA
Sodium Dihydrogen Phosphate Dihydrate

Dibasic Sodium Phosphate
Sodium Chloride
Tween-80
Purified Water

6.2 Incompatibilities:
None known.

6.3 Shelf life:
24 months.

6.4 Special precautions for storage:
Store in a cool dark place.
Shake well before Use.

6.5 Nature and contents of container:
5 ml sterile opaque plastic bottle with white cap packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling:
This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the tip to the eye or to any other surface.

The use of the product by more than one person may spread infection.

Keep the bottle tightly closed when not in use.

There are no special precautions for disposal.

7. Marketing authorization holder:
M/s. LinKabs Pharmaceuticals Ltd.,
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Fegge- Onitsha Box 10239,
Onitsha, Nigeria