

DESCRIPTION

Each ml contains:

Prednisolone Acetate USP	10mg
Ofloxacin USP	3mg
Benzalkonium Chloride USP	0.05 mg
Purified Water IP	q.s.

Prednisolone Acetate Actions:

Prednisolone Acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilatation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen and scar formation.

Ofloxacin Actions:

Ofloxacin is a fluorinated carboxyquinolone anti-infective for topical ophthalmic use. It is bactericidal in action and exerts its effect by inhibiting DNA gyrase, an essential bacterial enzyme that is a critical catalyst in the duplication, transcription and repair of bacterial enzyme.

Ofloxacin has been shown to be active in vitro activity against a broad range of gram positive and gram negative aerobic and anaerobic bacteria, both in vitro and clinically.

Aerobes gram positive:

Staphylococcus aureus, *Staphylococcus epidermis* and *Streptococcus pneumoniae*.

Aerobes gram negative:

Enterobacter cloacae, *Haemophilus influenzae*, *Proteus mirabills*. *Pseudomonas aeruginosa* and *Serratia marcescens*.

Anaerobic

Propionibacterium acnes.

species:



EXOPRED™
(Ofloxacin 0.3% + Prednisolone Acetate 1.0%)

Ofloxacin has been shown to be active in vitro against strains of these organisms but the clinical significance of ophthalmologic infections is unknown.

Aerobes gram positive: *Enterococcus faecalis*, *Listeria monocytogenes*, *Staphylococcus capitis*, *Staphylococcus hominis*, *Staphylococcus simulans* and *Streptococcus pyogenes*.

Aerobes gram negative : *Acinetobacter calcoaceticus* var. *anitratus*, *Acinetobacter calcoaceticus* var. *lwoffii*, *Citrobacter diversus*, *Citrobacter freundii*, *Enterobacter aerogenes*, *Enterobacter agglomerans*, *Escherichia coli*, *Haemophilus parainfluenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Moraxella* (*Branhamella*) *catarrhalis*, *Moraxella lacunata*, *Neisseria gonorrhoeae*, *Pseudomonas fluorescens*, *Shigella sonnei*.

Other: *Chlamydia trachomatis*.

INDICATIONS:

Where ever inflammation and infection co-exists. Mainly for post cataract inflammation control. Also for steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

Ofloxacin ophthalmic solution is indicated for the treatment of conjunctivitis, corneal ulcers, external infections of the eye and ocular surfaces caused by various gram negative and gram positive bacteria and anaerobic species.

CONTRAINDICATIONS:

Acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most viral diseases of the cornea and conjunctiva, ocular tuberculosis, and fungal diseases of the eye, and sensitivity to the drug. It is contraindicated in patients with history of hypersensitivity to Ofloxacin, to other quinolones, or to any of the components in this medication.

WARNINGS:

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids.

2. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids.

3. Use of steroid medication in presence of stromal herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.

4. As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasion may be suspected in persistent corneal ulceration where a steroid has been used, or is in use.

5. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in damage to the optic nerve with defects in the visual field. It is advisable that the intraocular pressure be checked frequently.

Use in Pregnancy:

Safety of Intensive or protracted use of topical steroids during pregnancy has not been substantiated.

Nursing Mother:

Because of the potential for serious adverse reactions from Ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric use:

Safety and effectiveness in infants below the age of one year has not been established.

NOT FOR INJECTION:

Use the solution within one month after opening the container. Do not touch the nozzle tip to any surface since this may contaminate the solution. If irritation persists or increases discontinue use and consult physician. Indiscriminate and prolonged use of the preparation may lead to glaucoma, cataract and fungal infections. Ofloxacin should not be injected subconjunctivally nor should it be introduced

directly into the anterior chamber of the eye. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose have been reported in patients receiving systemic quinolones, Including Ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial oedema), airway obstruction, dyspnea, urticaria and itching. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management including intubation should be administered as clinically indicated.

PRECAUTIONS:

Posterior sub capsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids. Patients with histories of herpes simplex keratitis should be treated with caution. As with other anti-infectives, prolonged use may result in overgrowth of non susceptible organisms, including fungi. If super infection occurs discontinue use and Institute alternative therapy.

ADVERSE REACTIONS:

Increased intraocular pressure, with optic nerve damage, defects in the visual fields, Also posterior sub capsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, and perforation of the globe when used in conditions where there is thinning of the cornea or sclera. Systemic side effects may occur with extensive use of steroids.

The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions include stinging, redness, itching, chemical conjunctivitis-keratitis, perocular/facial edema, foreign body sensation, photophobia, blurred vision, tearing, dryness and eye pain. Rare reports of dizziness have been received.

DOSAGE AND ADMINISTRATION:

1 to 2 drops instilled into conjunctival sac two to three

times daily. During the initial 24 to 48 hours the dosage may safely be increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

Overdosage : Clinically apparent symptoms of overdosage may be seen as punctate keratitis, erythema, lid edema, etc. the drug should be withheld and appropriate change in therapy instituted.

How Supplied: Exopred- is supplied in sterile 5ml plastic dropper bottles.

Note: Store in a cool dry place. Protect from light. Shake well before use.

KEEP MEDICATION OUT OF REACH OF CHILDREN.

DESCRIPTION:

Each tnl contains

- Fluorometholone USP 1 mg
- Neomycin Base
(added as Neomycin Sulphate IP) 3.5 mg
- Benzalkonium Chloride USP 0.04 mg

ACTIONS:

Corticosteroids, such as fluorometholone, inhibit the inflammatory response to a variety of inciting agents. They inhibit the edema, fibrin deposition, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. Corticosteroids inhibit the synthesis of histamine within mast cells by blocking the action of histidine decarboxylase. Corticosteroids also decrease prostaglandin synthesis and retard epithelial regeneration. Corticosteroids and their derivatives are capable of producing a rise in intraocular pressure.

In clinical studies on patients eyes treated with both Dexamethasone 0.1%, Fluorometholone 0.1%, Fluorometholone demonstrated a lower propensity to increase intraocular pressure than did Dexamethasone.

Neomycin is a broad spectrum bactericidal antibiotic effective against a variety of gram-positive and gram-negative organisms such as Staphylococcus aureus, Escherichia coli, Haemophilus influenzae, Klebsiella/Enterobacter species, Neisseria species, Proteus and Corynebacterium. Pus exudates and bacteria growth products do not inactivate the antibiotic.

INDICATIONS:

FML-NEO™ is effective in the treatment of infectious



conjunctivitis due to organisms sensitive to neomycin FML-NEO™ may be used for the treatment of anterior segment inflammatory disorders which may be threatened with or complicated by bacteria sensitive to neomycin. FML-NEO™ is effective following removal of foreign bodies as well as before and after surgery where the possibility of infection with susceptible organisms exists.

CONTRAINDICATIONS:

Acute untreated purulent ocular infections caused by micro-organisms not sensitive to Neomycin. Acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella, and most other viral diseases of the conjunctiva and the cornea. Ocular tuberculosis. Fungal diseases of the eye. Hypersensitivity to drug.

WARNINGS:

- In diseases due to microorganisms resistant to Neomycin, infection may be masked, enhanced or activated by the steroid. Prolonged use may result in overgrowth of nonsusceptible organisms.
- Articles in current medical literature indicate an increase in the prevalence of persons sensitive to Neomycin. The possibility of such a reaction should be borne in mind.
- If sensitivity or other untoward reactions occur, discontinue the medication.
- As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasions may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use, over a prolonged period of time.
- Various ocular diseases and long term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal and scleral tissues may lead to perforation.
- Acute purulent untreated infections of the eye may be masked, or activated by the presence of steroid medication. Secondary ocular infection may occur from pathogens liberated from ocular tissues.
- Use of steroid medication in the treatment of patients with a history of herpes simplex requires great caution, frequent

slit-lamp microscopy is required. • Reports in the literature indicate that posterior subcapsular lenticular opacities have occurred after heavy or protracted use of topical ophthalmic corticosteroids. • Prolonged use of topical steroids may increase intraocular pressure. Although currently available data indicate that intraocular pressure rise is generally not a problem with patients being treated with Fluorometholone 0.1%, their intraocular pressure should be checked periodically.

NOT FOR INJECTION. Use the solution within one month after opening the container Do not touch the nozzle tip to any surface since this may contaminate solution. If irritation persists or increases discontinue use and consult the physician. Indiscriminate and prolonged use of the preparation may lead to glaucoma, cataract and fungal infections.

DOSAGE & ADMINISTRATION:

1 to 2 drops in the conjunctival sac two to four times daily. During the initial 24-48 hours, the dosage may be safely increased to 1 drop every hour. Care should be taken not to discontinue treatment prematurely:

HOW SUPPLIED:

FML-NEO™ is available as a sterile suspension in 5 ml plastic dropper bottles.

Note: Store in a cool place. On prescription only. Protect from freezing. Shake well before use.

DESCRIPTION

Each ml contains;

Tobramycin Sulphate USP	
equivalent to Tobramycin	3mg
Fluorometholone USP	1mg
Benzalkonium Chloride USP	0.05 mg

Fluoromtholone Actions:

Corticosteroids, such as Fluorometholone, inhibit the inflammatory response to a variety of inciting agents. They inhibit edema, fibrin deposition, capillary dilation & perforation, leukocyte migration, phagocytic activity, deposition of collagen and scar formation associated with inflammation. Corticosteroids inhibit the synthesis of histamine within the mast cells. They also decrease prostaglandin synthesis and retard epithelial regeneration. Corticosteroids are capable of raising the intra ocular pressure.

Tobramycin Actions:

Tobramycin is an Aminoglycoside antibiotic obtained from the cultures of *Streptomyces tenebranius*. Tobramycin is bactericidal in action and exerts its effect by inhibiting protein synthesis by binding irreversibly to 30 S ribosomal subunits. Tobramycin has been shown to be active *in-vitro* against Staphylococci including *S. aureus* and *S. epidermidis*, including penicillin resistant strains.

Streptococci including *S. pneumoniae*, *Pseudomonas aeruginosa*, *Eschenchia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Haemophilus influenzae*, *Acinetobacter calcoaceticus* & some *Neisseria* species. Bacterial susceptibility studies demonstrate that in some cases microorganisms resistant to Gentamycin retain



FML-T™
(Fluorometholone 0.1% + Tobramycin 0.3%)

susceptibility to Tobramycin. Bacterial resistance may develop upon prolonged use.

INDICATIONS:

1. FML-T is effective in treatment of infectious conjunctivitis due to organisms sensitive to Tobramycin.
2. FML-T may be used for the treatment of the anterior segment inflammatory disorders which may be threatened with or complicated by bacteria sensitive to Tobramycin.
3. FML-T is effective following removal of foreign bodies as well as before and after surgery where the possibility of infection with susceptible organisms exists.

CONTRAINDICATIONS:

Acute superficial herpes simplex (dendritic keratitis), vaccinia, varicella and most viral diseases of the cornea and conjunctiva, ocular tuberculosis, and fungal diseases of the eye, and sensitivity to the drug. It is contraindicated in patients with history of hypersensitivity to Tobramycin, or to any of the components in this medication.

WARNINGS:

1. In those diseases causing thinning of the cornea, perforation has been reported with the use of topical steroids.
2. Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids.
3. Use of steroid medication in presence of stromal herpes simplex requires caution and should be followed by frequent mandatory slit-lamp microscopy.
4. As fungal infections of the cornea have been reported coincidentally with long-term local steroid applications, fungal invasion may be suspected in persistent corneal ulceration where a steroid has been used, or is in use.
5. Use of topical corticosteroids may cause increased intraocular pressure in certain individuals. This may result in

damage to the optic nerve with defects in the visual field. It is advisable that the intraocular pressure be checked frequently.

Use In Pregnancy:

Safety of intensive or protracted use of topical steroids during pregnancy has not been substantiated. Category B Reproduction studies in animals using systemic tobramycin dosages up to 33 times the usual human systemic dosage have not revealed evidence of impaired fertility or harm to fetus. There are however no controlled studies to date using topical or systemic tobramycin in pregnant women and ophthalmic tobramycin should be used during pregnancy only when clearly needed.

Nursing Mothers:

Because of the potential for serious adverse reactions from tobramycin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Not for Injection:

Use the solution within one month after opening the container. Do not touch the nozzle tip to any surface since this may contaminate the solution. If irritation persists or increases discontinue use and consult physician. Indiscriminate and prolonged use of the preparation may lead to glaucoma, cataract and fungal infections.

PRECAUTIONS:

Posterior sub capsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids. Patients with histories of herpes simplex keratitis should be treated with caution. As with other antiinfectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super infection occurs discontinue use and institute alternate therapy.

ADVERSE REACTIONS:

Increased intraocular pressure, with optic nerve damage, defects in the visual fields, Also posterior sub capsular cataract formation, secondary ocular infections from fungi or viruses liberated from ocular tissues, and perforation of the globe when used in conditions where there is thinning of the cornea or sciera. Systemic side effects may occur with extensive use of steroids.

The most frequently reported drug-related adverse reaction was transient ocular burning or discomfort. Other reported reactions include increased lacrimation, itching and edema of the eyelid and Conjunctival erythema. These reactions occur in less than 3% of patients receiving ophthalmic tobramycin and usually disappear when the drug is discontinued.

DOSAGE AND ADMINISTRATION:

ito 2 drops instilled into conjunctival sac two to three times daily. During the initial acute phase the dosage may safely be increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

Overdosage : Clinically apparent symptoms of overdosage may be seen as punctate keratitis, erythema, lid edema, etc. the drug should be withheld and appropriate change in therapy instituted.

How Supplied: FML-T™ (Fluorometholone plus Tobramycin ophthalmic suspension) is supplied in sterile 5ml plastic dropper bottles.

Note: Store in a cool dry place. Shake well before use.

KEEP MEDICATION OUT OF REACH OF CHILDREN