

AFM-Plus

Fluorometholone 0.1% &
Gentamicin 0.3%
Ophthalmic Suspension and Ointment

Composition:

AFM-Plus Ophthalmic Suspension: Each ml contains Fluorometholone USP 1 mg & Gentamicin Sulfate USP equivalent to Gentamicin 3 mg.

Preservative : Benzalkonium Chloride Solution BP 0.01%.

Vehicle : HPMC USP 0.5%.

AFM-Plus Eye Ointment: Each gram contains Fluorometholone USP 1 mg & Gentamicin Sulfate USP equivalent to Gentamicin 3 mg.

Pharmacology:

Gentamicin belongs to the group of aminoglycoside antibiotics. It covers a broad spectrum of Gram-positive and Gram-negative pathogens, including *Pseudomonas aeruginosa*, *Staphylococci*, *Haemophilus influenzae*, *H. aegypticus*, *Klebsiella*, *Enterobacteria*, *Proteus*, *Escherichia coli*, *Shigella* and *Salmonella*. It inhibits specifically bacterial protein synthesis. Fluorometholone is a synthetic fluorinated corticosteroid possessing anti-inflammatory properties. The combination brings concomitantly the bacterial treatment or prophylaxis and the anti-inflammatory effect. In addition, the presence of gentamicin protects from a risk of potential aggravation of a bacterial infection due to the steroid.

Indications:

Inflammation associated with infections in the anterior segment of the eye due to bacteria susceptible to Gentamicin. It is also indicated in postoperative infection.

Dosage & administration:

Ophthalmic Suspension

Bacterial infection:

The dosage depends on the severity of the disease. The application of 1 drop 5 times daily into the conjunctival sac of the affected eye is recommended. In severe cases the dosage can be increased up to 1 drop per hour for 1 to 2 days.

Ocular postoperative infection:

1 drop 4 times daily into the conjunctival sac for 1 week. Then a reduced application frequency is recommended for the remaining part of the treatment.

Eye Ointment:

Bacterial infection:

Apply 3-4 times daily into the affected eye.

Ocular postoperative infection:

To support the therapy with Ophthalmic Suspension during the night apply ointment before retiring.

Contraindications:

- Hypersensitivity to any of the components. Injuries and ulceration of the cornea. Viral infections (e.g. Herpes simplex, Vaccinia) or mycosis.
- Eye tuberculosis.
- Glaucoma.

Precautions and warnings:

- Steroids can mask, activate or aggravate ocular infections.
- Long term treatment with steroid may enhance thinning of cornea and sclera and rarely perforation of the cornea has been reported.
- In case no improvement is observed after 7-8 days of treatment, other therapeutical means should be considered.
- Patients experiencing blurred vision after application of the product, particularly the ointment, should refrain from driving vehicles or operating machinery.
- Contact lenses should be removed before each application.

Side-effects:

A transient burning sensation may occur after instillation.

Rare: Hypersensitivity reactions including eczema of the eyelid and puncture keratitis. Prolonged use of topical steroids may delay wound healing, increase of IOP, develop cataract and cause thinning of cornea & sclera.

Pregnancy and lactation:

No controlled studies in humans are available. Administration during pregnancy and lactation is therefore not recommended, except for compelling reasons.

Storage:

- Store below 30°C at dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

AFM-Plus Ophthalmic Suspension: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.

AFM-Plus Eye Ointment: Each tube contains 3 g Sterile Eye Ointment.



Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH

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