

PRESCRIBING INFORMATION

Fusidic Acid 1% Eye Drops

(fusidic acid)

Presentation: Contains 10 mg fusidic acid per gram, in a viscous eye drop formulation.

Indication: For the topical treatment of bacterial conjunctivitis where the organism is known to be sensitive to the antibiotic.

Dosage and Administration: For ophthalmic use only. *For all ages:* One drop to be instilled into the eye twice daily. Treatment should be continued for at least 48 hours after the eye returns to normal.

Contraindications: Hypersensitivity to fusidic acid/sodium fusidate, or any of the excipients.

Precautions and warnings: Contact lenses should not be worn/ used, since microcrystalline fusidic acid may cause scratches in the contact lens or cornea. Contains benzalkonium chloride which may cause eye irritation and is also known to discolour soft contact lenses. Bacterial resistance has been reported to occur with the use of fusidic acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

Interactions: None known.

Pregnancy and lactation: Clinical experiences with systemic and topical fusidic acid suggest that fusidic acid is devoid of teratogenic effect and hence can be administered during pregnancy if considered necessary. The effects of fusidic acid on breastfeeding infants is negligible and can be used during breastfeeding.

Undesirable effects: Undesirable effects have been reported in approximately 10% of the patients; primarily short lasting local discomfort in the form of stinging and burning sensation. Most frequently reported adverse events are various application site reaction such as transient stinging and burning sensation or transient blurring of vision. Commonly reported undesirable effects at the site of administration are burning, stinging, discomfort, smarting, irritation, itching, soreness, dryness in the eyes and transient blurring of vision.

(Please refer Summary of Product Characteristics for detailed information)

Overdose: Overdosage is unlikely to occur. Unless hypersensitivity to fusidic acid or any of the excipients exists, accidental ingestion is unlikely to cause any harm. The concentration of the excipients is too low to constitute a safety risk.

Legal category: POM

Basic NHS cost and pack size: £7.57 per 5g tube **Marketing Authorisation Number:** PL 20072/0242

Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL

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Adverse events should be reported to the local regulatory authority.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to
Amdipharm Mercury Medical Information via telephone on **08700 70 30 33** or
via e-mail at medicalinformation@amcolimited.com.