

Data Sheet

Fucithalmic[®]

Fusidic Acid Eye Drops

Qualitative and Quantitative Composition

Each gram contains fusidic acid anhydrous 10 mg as fusidic acid hemihydrate
Ph.Eur.

Pharmaceutical Form

Sterile viscous eye drops of 1% aqueous sustained release formulation of fusidic acid (microcrystalline suspension) in a carbomer gel. Fucithalmic[®] liquefies and becomes clear on contact with the electrolytes of the tear fluid, and therefore causes less blurring of vision than eye ointment. The viscosity of the carbomer allows easy administration and gives rise to prolonged concentrations of fusidic acid in the tear fluid.

Clinical Particulars

USES

Actions

Fucithalmic[®] is an antimicrobial agent that inhibits bacterial protein synthesis. Fucithalmic[®] kills a wide range of gram-positive organisms. It is used to treat bacterial eye infections.

Indications

Fucithalmic[®] is indicated for the topical treatment of bacterial eye infections where the organism is sensitive to the antibiotic. These may include: bacterial conjunctivitis, blepharitis, sty, and keratitis.

Dosage and Administration

For all ages: One Fucithalmic[®] 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 any of its components.

Special Warnings and Precautions for Use

Contact lenses should not be worn/used when Fucithalmic[®] is used. The microcrystalline fusidic acid may cause scratches in the contact lens or cornea. Fucithalmic[®] eye drops contain benzalkonium chloride, which is known to discolour soft contact lenses.

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Fucithalmic[®] eye drops are preserved with benzalkonium chloride. Benzalkonium chloride may cause eye irritation.

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 with Other Medicaments and Other Forms of Interaction

Not applicable

Pregnancy and Lactation

Pregnancy

There are no clinical data on exposed pregnancies available, but animal studies and many years of clinical experience with systemic and topical fusidic acid suggest that fusidic acid is devoid of teratogenic effect. Consequently any risk to the foetus is unlikely using the very low doses of fusidic acid applied topically in Fucithalmic[®].

Lactation

No effects on the suckling child are anticipated since the systemic exposure of the breastfeeding woman to fusidic acid is negligible. Fucithalmic[®] eye gel can be used during breastfeeding.

Effects on Ability to Drive and Use Machines

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

Adverse Effects

Very common $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ and $< 1/1,000$

Very rare $< 1/10,000$

Pooled data from clinical studies, including more than 1,500 patients with acute conjunctivitis, showed that undesirable effects occurred in approximately 10% of the patients; primarily short lasting local discomfort in the form of stinging and burning sensation.

The most frequently reported adverse drug reactions are various application site reactions such as transient stinging and burning sensation or transient blurring of vision. Urticaria, rash and allergic reactions have been reported.

Immune System Disorders:

Uncommon:

Allergic reaction

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Eye Disorders:

Common:

Eye burning
Eye stinging

Uncommon:

Eyes tearing
Transient blurring of vision

Rare:

Conjunctivitis aggravated

Skin and Subcutaneous Tissue Disorders:

Uncommon:

Pruritus
Periorbital oedema

Rare:

Rash
Urticaria
Angiooedema

General Disorders and Administration Site Reactions:

Common:

Application site reaction

Overdosage

Not applicable.

Pharmacological properties

Pharmacodynamic Properties

Fusidic acid exerts its antimicrobial action by inhibition of bacterial protein synthesis. Fucithalmic[®] is active against a wide range of gram-positive organisms, particularly *Staphylococcus aureus*. Other species against which Fucithalmic[®] has been shown to have *in vitro* activity include *Streptococcus*, *Neisseria*, *Haemophilus*, *Moraxella* and *Corynebacteria*. *Pseudomonas* and *Enterobacteriaceae* spp. are not sensitive to fusidic acid. *In vivo* fusidic acid is not active against *Chlamydia trachomatis*.

Pharmacokinetic Properties

The sustained release formulation of Fucithalmic[®] ensures a prolonged contact with the conjunctival sac. Twice daily application provides sufficient fusidic acid concentrations in all relevant tissues of the eye. Fusidic acid penetrates well into the aqueous humour.

The biological half-life of Fucithalmic[®] is 7.3 hours and mean antibiotic concentrations after a single dose of one drop 12 hours after administration are 6.0 mcg/mL.

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Pharmaceutical Particulars

List of Excipients

Benzalkonium chloride, disodium edetate, mannitol, carbomer, sodium hydroxide and water for injections.

Pharmaceutical Precautions

Incompatibilities

None known.

Shelf Life

3 years.

Special Precautions for Storage

Store below 30°C. Keep the tube tightly closed. The tube should be discarded one month after opening.

Presentation

Package Quantities

5g tube with tamper-evident cap

Instructions for Use/Handling

None

Medicine Classification

Prescription Medicine

FURTHER INFORMATION

Not Applicable

Name and Address

Under Licence from:

LEO Pharmaceutical Products Ltd. A/S
Industriparken 55
Ballerup
Denmark

Data Sheet

Distributed in New Zealand by:

CSL Biotherapies (NZ) Ltd
666 Great South Road
Penrose Auckland 1544
New Zealand

Telephone number: 0800 502 757

Date of Preparation

30 June 2011

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