1 Fucithalmic®

Fucithalmic 1% w/w Viscous Eye Drops

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains fusidic acid, hemihydrate 10mg.

Excipient with known effect: 0.01% w/w benzalkonium chloride

For the full list of excipients, see section 6.1

3 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.

4 CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of 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.

4.3 Contraindications

Hypersensitivity to any of its components.

4.4 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.

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.

4.5 Interaction with other medicines and other forms of interaction

Not applicable

4.6 Fertility, 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 fetus is unlikely using the very low doses of fusidic acid applied topically in Fucithalmic®.

Breast-feeding

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.

4.7 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.

4.8 Undesirable effects

Very common ≥1/10
Common ≥1/100 and <1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥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

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose
For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antimicrobial, ATC code: S01AA13

Mechanism of action

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. Psueudomonas* and *Enterobacteriaceae spp.* are not sensitive to fusidic acid. *In vivo* fusidic acid is not active against *Chlamydia trachomatis.*

5.2 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 µg/mL.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the datasheet.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzalkonium chloride, disodium edetate, mannitol, carbomer, sodium hydroxide and water for injections.

6.2 Incompatibilities
None known.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store below 25°C. Keep the tube tightly closed. The tube should be discarded 28 days after opening.

6.5 Nature and contents of container
5g tube with tamper-evident cap

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

AFT Pharmaceuticals Ltd
PO Box 33-203
Takapuna
Auckland 0740
Phone: 0800 423 823
Email: customer.service@aftpharm.com

9 DATE OF FIRST APPROVAL

8 September 1988

10 DATE OF REVISION OF THE TEXT

December 2020

Summary table of changes:

Section changed	Summary of new information
6.4	Change in in-use shelf life of the product from 1 month to 28 days