1. NAME OF THE MEDICINAL PRODUCT

Fucithalmic 10 mg/g eye drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of eye drops contains 10 mg fusidic acid.

Excipient with known effect: benzalkonium chloride.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, suspension.
Description of the medicinal product: viscose, white or yellowish suspension in water.

4. CLINICAL PARTICULARS

4.1 Indications

Eye infections, including keratitis, conjunctivitis, meibomitis, blepharitis, caused by bacteria susceptible to fusidic acid.

4.2. Posology and method of administration

1 drop twice a day. Initially, more frequent dosage may be used; in addition, the eye should be cleaned frequently. For prevention of recurrence, treatment should be continued for at least 2 days after the symptoms have subsided.

4.3. Contraindications

Hypersensitivity to fusidic acid, sodium fusidate, or any of the excipients mentioned in

section 6.1.

4.4. Special Warnings and precautions for Use

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.

Contact lenses should not be worn/used when Fucithalmic is used. Microcrystalline fusidic acid may cause scratches in the contact lens or cornea. Contact lenses may be worn 12 hours after discontinuation of treatment.

Fucithalmic contains benzalkonium chloride which may cause eye irritation and discolouration of soft contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been conducted. Systemic infections are unlikely since the systemic effect of the use of Fucithalmic eye drops is negligible.

4.6. Fertility, pregnancy and lactation

Pregnancy
Because the systemic absorption of Fucithalmic eye drops is insignificant, no effect on pregnancy is expected. Fucithalmic eye drops can be used during pregnancy.

Lactation
No harmful effect on the nursing infant is anticipated since the systemic exposure on the breastfeeding woman to fusidic acid is negligible. The medicinal product can be used during lactation.

Fertility
No clinical studies have been conducted concerning the effect of Fucithalmic drops on fertility. Since systemic absorption of Fucithalmic eye drops is negligible, no effect on fertility is anticipated.

4.7. Effects on ability to drive and use machines

Fucithalmic drops do not have an effect on the ability to drive and using machines, or said effect is negligible. The patients should be aware of that Fucithalmic may cause transient blurring of vision following application of the drops.

4.8. Adverse effects

The estimation of the frequency of undesirable effects is based on pooled data from clinical studies and spontaneous reports.

The most frequently reported undesirable effects during treatment, occurring in 8.5% of the patients were application site reactions, including pain, itching and irritation/discomfort inside or outside the eyes.
The next common undesirable effect was blurred vision in 1.2% of the patients. Postmarketing reports have shown angio-oedema in a few patients.

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported. In each category, the undesirable effects are listed starting with the most serious ones in descending order.

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

Immune system disorders	
Uncommon: (≥1/1,000 and <1/100)	Hypersensitivity
Eye disorders	
Common: (≥1/100 and <1/10)	Transient blurring of vision

Uncommon: (≥1/1,000 and <1/100)	Eyelid oedema Watery eyes
Rare: (≥1/10,000 and <1/1,000)	Aggravated conjunctivitis
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Angio-oedema Itching
Rare: (≥1/1,000 and <1/100)	Urticaria
General disorders and administration site conditions	
Common: (≥1/100 and <1/10)	Administration site pain (including burning sensation and stinging in the eye). Application site itching. Application site irritation.

Paediatric patients
The observed safety profile of the medicinal product is similar in children and adults.

4.9. Overdose

The total quantity of fusidic acid in one 5g tube of Fucithalmic (50mg) will not exceed the approved total daily oral dose of fusidic acid containing medicinal products. The concentration of the excipients is too low to constitute a safety risk. Thus, overdosing is unlikely.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group, ATC-code: S01AA13

Fusidic acid is active against S*taphylococcus aureus* in particular and *Staphylococcus epidermidis* regardless of their production of beta-lactamase. Streptococci and *Neisseria* spp. are susceptible as well. Enterobacteria and *Neisseria* spp. are resistant. There is no cross-resistance between fusidic acid and other antibiotics.

5.2. Pharmacokinetic properties

The tear fluid and the aqueous humour contain effective concentrations of fusidic acid for at least 12 hours after application of one drop of Fucithalmic. Average fusidic acid concentrations in the tear fluid are after 1, 3, 6 and 12 hours after application of one drop 15.7 mg/L, 15.2 mg/L, 10.5 mg/L, and 5.6 mg/L, respectively. Fusidic acid penetrates across the undamaged cornea as well after surgery. In the aqueous humour, the concentration of fusidic acid is on average 0.3 mg/L for at least 12 hours after application of one drop. Said concentration is higher than the MIC-values of most relevant bacteria (*S. aureus* MIC_{90} = 0.06 mg/L).

5.3. Preclinical safety data

Preclinical data do not show a particular risk to humans.

The teratogenicity of sodium fusidate was studied in albino rats –mice and rabbits.
Sodium fusidate was administered as a water solution (by gavage) to rats and mice and as tablets to rabbits.
None of the three animal species showed signs of teratogenicity (malformation) compared to animal controls. (*Laboratory testing of fucidin for teratogenic properties_LEO Report 1965*).

Sodium fusidate was administered 400 mg/day to male and female rats two weeks from copulation until weaning of pups. Caesarean section was performed to half of the mothers on day 20. Developmental parameters of the uteral phase and newborn pups were compared with the control group not receiving the medicinal product. Compared to the control group, sodium fusidate did not have any effect on fertility, uterus function or development of the newborn. (*Reproduction and lactation studies_LEO Report 1966)*.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

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

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years. The shelf life of an opened package is 28 days.

6.4. Storage

Store below 25℃.

6.5. Nature and contents of container

5 g tube. The tube is manufactured of polyethylene (HDP).

6.6. Special precautions for disposal and other handling

None.
Unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Amdipharm Limited
Temple Chambers

3 Burlington Road
Dublin 4
Ireland

8. MARKETING AUTHORISATION

NUMBER

9996

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14.06.1989/27.01.2009

10. DATE OF REVISION OF THE TEXT

19.4.2013