Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucithalmic 10mg/g Viscous Eye Drops, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 1 % w/w fusidic acid anhydrous (as the hemihydrate).

Excipient with known effect: contains 0.011% w/w benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension (eye drops)
A white to off-white viscous suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of ocular infection due to sensitive organisms.

4.2 Posology and method of administration

Posology:
One drop of Fucithalmic viscous eye drop, should be applied to the conjunctival sac every 12 hours. Treatment should be continued for 2 days after the eye appears normal.

Method of administration:

For ophthalmic use only.

Direction for use for administration:

1. As with any eye preparation, wash your hands before you administer Fucithalmic viscous eye-drops.
2. Remove the cap from the tube. To administer Fucithalmic viscous eye-drops, stand or sit comfortably and tilt your head backwards. Hold the tube above your eye.
3. Gently pull down your lower eyelid and squeeze one drop from the tube into your lower eyelid as shown in the picture. You may find a mirror useful when administering the drops.
4. Be careful not to touch the tip of the tube to your eye or other surface, so as to avoid contamination of tube contents.
5. Fucithalmic viscous eye-drops comes out of the tube as a single viscous drop, which quickly turns to liquid in your eye.
6. If the drops are for children, you may put the drops in their eyes when they are lying down or asleep.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed 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 of fusidic acid may increase the risk of developing antibiotic resistance.

Contact lenses should not be worn during Fucithalmic treatment. The microcrystalline fusidic acid may cause scratches in the contact lens or cornea.

Fucithalmic viscous eye drops (in tube) contains benzalkonium chloride, which may discolour soft contact lenses. From the limited data available, there is no difference in the adverse event profile in children compared to adults. Generally, however, eyes in children show a stronger reaction for a given stimulus than the adult eye. Irritation may have an effect on treatment adherence in children. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed. Systemic interactions are unlikely since systemic exposure after application of Fucithalmic viscous eye drops is negligible.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to Fucithalmic viscous eye drops is negligible. Fucithalmic viscous eye drops can be used during pregnancy.

Breast-feeding
No effects on the breast-fed new-born/infant are anticipated since the systemic exposure of the breast-feeding woman to fusidic acid is negligible. Fucithalmic viscous eye drops can be used during breast-feeding.

Fertility
There are no clinical studies with topical Fucithalmic regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure to Fucithalmic viscous eye drops is negligible.

4.7 Effects on ability to drive and use machines

Fucithalmic viscous eye drops has no or negligible influence on the ability to drive or use machines. Fucithalmic viscous eye drops may, however, cause a blurring of vision following application and patients should take this into account.

4.8 Undesirable effects

The estimation of the frequency of undesirable effects is based on a pooled analysis of data from clinical trials and spontaneous reporting.

Based on pooled data from clinical studies, including 2,499 patients with eye infections including acute conjunctivitis, who received Fucithalmic viscous eye drops, the frequency of undesirable effects was 11.3%.

The most frequently reported adverse reactions during treatment are various application site reactions such as pain, pruritus and irritation/discomfort in/around the eyes, which occurred in approximately 8.5% of patients, followed by blurring of vision, which occurred in approximately 1.2% of patients. Angioedema has been reported in a few patients post marketing.

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported. Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness.

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)
Not known (cannot be estimated from the available data)

System organ class	Frequency	Undesirable effects
Immune system disorders	Uncommon	Hypersensitivity
Eye disorders	Common	Vision blurred (transient)
	Uncommon	Eyelid oedema Lacrimation increased
	Rare	Conjunctivitis aggravated
Skin and subcutaneous tissue disorders	Uncommon	Angioedema Rash
	Rare	Urticaria
General disorders and administration site conditions	Common	Application site pain (including eye burning and eye stinging) Application site pruritus Application site discomfort/irritation

Paediatric population
The observed safety profile is similar in children and adults.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

The total quantity of fusidic acid in one 5g tube of Fucithalmic viscous eye drops (50 mg) does not exceed the approved total daily oral dose of fusidic acid containing products. The concentration of the excipients is too low to constitute a safety risk. Therefore, overdose is unlikely to occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antimicrobial, ATC code: S 01 AA 13

Fucithalmic is active against a wide range of gram positive organisms, particularly *staphylococcus aureus*. Cross allergy between fusidic acid and other antibiotics has not been reported.

5.2 Pharmacokinetic properties

The formulation of Fucithalmic viscous eye drops ensures a prolonged contact with the conjunctival sac. Fusidic acid penetrates into aqueous humour.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Disodium edetate
Mannitol
Carbomer
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 3 years
After first opening container: Discard any remaining drops 28 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C. Keep cap tightly closed.

6.5 Nature and contents of container

Polyethylene laminated aluminium tube, with a HDPE cap, containing 5g and 3g of eye drops suspension.

Not all pack sizes may be marketed.

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 MARKETING AUTHORISATION HOLDER

Amdipharm Limited
Temple Chambers
3 Burlington Road
Dublin 4
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1142/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 April 1988

Date of last renewal: 27 November 2007

10 DATE OF REVISION OF THE TEXT

October 2021