Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucithalmic 2mg/0.2g Unit Dose, eye drops, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 g unit contains 2 mg of fusidic acid anhydrous (as the hemihydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension (eye drops)
A sterile, white, opalescent, viscous suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of ocular infection due to sensitive organisms.

4.2 Posology and method of administration

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

The contents of each Fucithalmic 2mg/0.2g Unit Dose container are sufficient for the treatment of both eyes if necessary.

4.3 Contraindications

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

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.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Pregnancy
Limited clinical data on exposed pregnancies is available. This data and animal studies and many years of clinical experience with systemic and topical fusidic acid suggest that fusidic acid is devoid of teratogenic effect.

No effects during pregnancy are anticipated, since systemic exposure to Fucithalmic® eye drops is negligible.
Fucithalmic® eye drops can be used during pregnancy if considered necessary.

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® eye drops can be used during breast-feeding.

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

4.7 Effects on ability to drive and use machines

Fucithalmic® eye drops has no or negligible influence on the ability to drive or to use machines. Fucithalmic® 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® 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

Immune system disorders
Uncommon ≥1/1,000 and <1/100
Hypersensitivity

Eye Disorders
Common (≥1/100 and <1/10):
Vision blurred (transient)

Uncommon (≥1/1,000 and <1/100):
Eyelid oedema
Lacrimation increased

Rare (≥1/10,000 and <1/1000):
Conjunctivitis aggravated

Skin and subcutaneous tissue disorders
Uncommon (≥1/1,000 and <1/100):
Angioedema
Rash

Rare ≥1//10,000 and <1/1,000
Urticaria

General disorders and administration site conditions
Common (≥1/100 and <1/10):
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

4.9 Overdose

The total quantity of fusidic acid in one pack of Fucithalmic® Unit Dose (24mg) 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: ATC code: S 01 AA 13

Fucithalmic® is active against a wide range of Gram positive organisms, particularly staphylococci. Cross allergy between fusidic acid and other antibiotics has not been reported.

5.2 Pharmacokinetic properties

The formulation of Fucithalmic 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

Carbomer
Mannitol
Sodium acetate
Sodium hydroxide (for pH adjustment)
Water for Injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 2 years
After first opening container: Any remaining contents in a single use container should be discarded after one use. Discard any remaining single use containers one month after opening foil pack.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

Strip of 12 single use LDPE containers packed in a pouch of laminated aluminium foil, polyethylene and paper. Each single use container contains 0.2 g of eye drop suspension.

6.6 Special precautions for disposal

No special requirements for disposal.

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

PA 1142/016/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 November 1992

Date of last renewal: 27 November 2007

10 DATE OF REVISION OF THE TEXT

March 2014