SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fucithalmic Viscous Eye Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fucithalmic Viscous Eye Drops contains Fusidic acid 1%.

Excipient with known effect:
One gram of Fucithalmic contains 0.11mg benzalkonium chloride.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops
A white to off-white viscous eye drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of external eye infections caused by microorganisms sensitive to the preparation.

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.

4.3 Contraindications

Hypersensitivity to the active substance, or to any of the excipients listed in Section 6.1.

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. Contact lenses are kept out until all symptoms of the infection have gone.

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.

Excipient warning:
Fucithalmic contains benzalkonium chloride, which may cause eye irritation and discolour soft contact lenses.

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 is negligible.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breast-feeding

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

Fertility

There are no clinical studies with Fusidic acid eye drops regarding fertility. No effects on women of childbearing potential are anticipated, since systemic exposure to Fusidic acid eye drops is negligible.

4.7 Effects on ability to drive and use machines

Fucithalmic has no or negligible influence on the ability to drive or use machinery. Fucithalmic may, however, cause a blurring of vision following application and patient 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)

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	Rash Angioedema
	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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

The total quantity of fusidic acid in one 5 g tube of Fucithalmic 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: S01AA13

Fusidic acid eye drops are active against a wide range of Gram-positive organisms, particularly *Staphylococcus aureus*.
Other species against which fusidic acid eye drops have been shown to have *in vitro* activity include *Streptococcus, Neisseria, Haemophilus, Moraxella* and *Corynebacteria*.

5.2 Pharmacokinetic properties

The 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.

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

Water for injection
Mannitol
Carbomer
Disodium edetate
Benzalkonium chloride
Sodium hydroxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25ºC. Keep the tube cap tightly closed.
The tube should be discarded 28 days after first opening.

6.5 Nature and content of container

Tube of 5g.

6.6 Special precautions for disposal and other handling

DIRECTIONS 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER:
Dexcel Ltd., 1 Dexcel Street, Or Akiva 3006000, Israel

8. MARKETING AUTHORISATION NUMBER:
057 82 26772 00

This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in July 2012 and updated according to the guidelines of the Ministry of Health in March 2020