Fusidic Acid 1% Viscous Eye Drops

Summary of Product Characteristics Updated 09-Jan-2024 | ADVANZ Pharma

1. Name of the medicinal product

Fucithalmic 1% w/w Viscous Eye Drops

Fusidic acid 1% w/w Viscous Eye Drops

2. Qualitative and quantitative composition

Each gram contains fusidic acid, hemihydrate 10mg.

Excipient with known effect:

0.011% w/w benzalkonium chloride

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Sterile viscous eye drops.

4. Clinical particulars

4.1 Therapeutic indications

Fusidic acid eye drops are indicated for the topical treatment of bacterial conjunctivitis where the organism is known to be sensitive to the antibiotic.

4.2 Posology and method of administration

Posology:

For all ages: One Fusidic acid eye drop to be instilled into the eye twice daily. Treatment should be continued for at least 48 hours after the eye returns to normal.

Method of administration:

For ophthalmic use only.

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 Fusidic acid eye drops are 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.

Fusidic acid eye drops contain 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 Fusidic acid eye drops 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. Fusidic acid 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. Fusidic acid eye drops 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

Fusidic acid eye drops has no or negligible influence on the ability to drive or use machines. Fusidic acid eye drops 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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 contain-ing 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 sustained release formulation of Fusidic acid eye drops 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 pre-clinical 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, water for injections.

6.2 Incompatibilities

Not applicable.

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 one month after opening.

6.5 Nature and contents of container

Available in 5g tubes.

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.

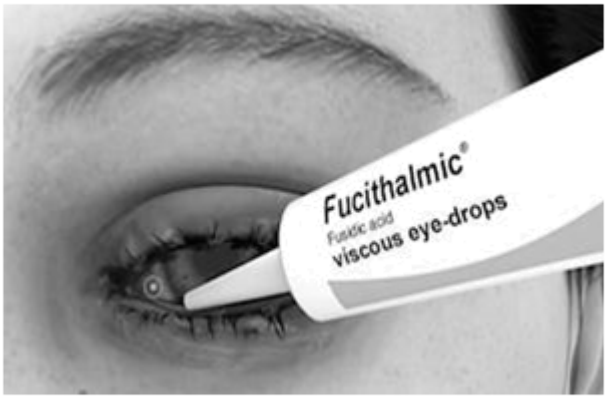
2. Remove the cap from the tube. To administer FUCITHALMIC viscous eye-drops, stand or sit comfortably and tilt your head backwards. Hold the tube above your eye.

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

Amdipharm UK Limited,

Dashwood House, 69 Old Broad Street,

London, EC2M 1QS, United Kingdom

8. Marketing authorisation number(s)

PL 20072/0242

9. Date of first authorisation/renewal of the authorisation

Date of first authorization: 10 August 1987

Date of latest renewal: 02 September 2013

10. Date of revision of the text

11/12/2023

Company Contact Details

ADVANZ Pharma
Address
Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK
Medical Information Direct Line
+44 (0)208 588 9131
WWW
www.advanzpharma.com
Telephone
+44 (0)208 588 9131
Medical Information e-mail
medicalinformation@advanzpharma.com
Customer Care direct line
+44 (0)208 588 9273