SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FUSIX 1% Viscous Eye Drops, Solution
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Fusidic acid hemihydrate 1.02% (equal to 1% mg Fusidic acid)

Excipients:
Benzalkonium chloride 0.01%
For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Viscous eye drops.
White or off-white homogenous viscous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FUSIX is used to treat:
- Conjunctivitis
- Blepharitis
- Hordeolum
- Keratitis
- Dacryocystitis
- Bacterial eye infections which are associated with foreign body removal.

4.2 Posology and method of administration

Posology/frequency and duration of administration
FUSIX, for all ages: One drop is dropped into the eye twice a day. Treatment should be continued for at least 48 hours after the eye returns to normal.

Method of administration
It is dropped into conjunctival sac in the eye.

Additional information on special populations

Renal/Hepatic impairment
There is no data related to the usage in renal and hepatic failure.

Pediatric population
The recommended dose for all age groups is one drop twice daily, morning and evening.

Geriatric population
The recommended dose for all age groups is one drop twice daily, morning and evening.

4.3 Contraindications
The drug should not be used in case of hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use
FUSIX eye drops contain benzalkonium chloride which may cause eye irritation and is also known to discolor soft contact lenses.
Like all ophthalmic preparations containing benzalkonium chloride, contact lenses should not be worn/used when FUSIX eye drops are used. During treatment with FUSIX, you should take care while using contact lenses.
Take your contact lenses out before administration and wait for at least 15 minutes before putting lenses back in.

Bacterial resistance has been reported to occur with the use of fusidic acid. As with all antibiotics, extended and recurrent use may increase the risk of developing the resistance.

After being opened, it should be used in 15 (fifteen) days.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction has been reported.
When other ocular preparations are to be used, 5 minutes interval should be set between administrations of 2 preparations.

4.6 Fertility, pregnancy and lactation

General recommendation
Pregnancy category: B.

Women of child-bearing potential/Contraception
There is no clinical data available regarding the exposure during pregnancy for FUSIX.

Pregnancy
There is no sufficient data regarding the usage in pregnancy. However, it can be used after the benefit/risk ratio is assessed by the physician.
Animal studies suggest that fusidic acid is devoid of toxic effect on fetus. Consequently any risk to the fetus toxicity is unlikely using the low doses of fusidic acid related to FUSIX usage.

Breast-feeding
It is not known, whether fusidic acid hemihydrate is excreted via breast milk. Excretion of fusidic acid hemihydrates through breast milk has not been studied on animals. When deciding whether or not stop breast-feeding or avoid FUSIX therapy or not, benefit of breast-feeding for the child and benefit of FUSIX therapy for breast-feeding mother should be taken into consideration.

Fertility
There is no data regarding the effect on fertility.

4.7 Effects on ability to drive and use machines
Fusidic acid eye drops may cause negligible, transient blurring of vision following application.

4.8 Undesirable effects
Pooled data from clinical studies, including more than 2600 patients with acute conjunctivitis, showed that undesirable adverse effects occurred in approximately 10% of the patients, primarily in application site in the form of stinging and burning sensation.
The most frequently reported side effects that are observed in application site are transient stinging and burning sensation and transient blurring of vision.
Side effects that are observed with fusidic acid are listed in system organ class as below:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Immune system disorders:
Rare: Hypersensitivity

Eye diseases:
Common: Stinging in administration site, burning, discomfort, tingling, irritation, itching, soreness, dryness sensation, transient blurring of vision.
Uncommon: Watery eyes on application
Not known: Conjunctivitis aggravated.

Skin and subcutaneous disorders
Not known: Pruritus, periorbital edema, rash, urticaria, angioedema.

Additional ınformation for special populations:
Pediatric Population:
The observed safety profile is similar in children and adults.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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 national reporting system.

4.9 Overdose
Overdosage is unlikely to occur.
Unless hypersensitivity to fusidic acid or any of the excipients exists, accidental ingestion of FUSIX is unlikely to cause any harm. The total quantity of fusidic acid (50 mg) in one 5 g tube of FUSIX will not exceed the approved total daily oral dose. The concentration of the excipients is also too low to constitute a safety risk.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Ophthalmologic antibiotic.
ATC code: S01AA13

Fusidic acid is a narrow-spectrum antibiotic, highly active against *Staphylococcus aureus, Staphylococcus epidermidis, Corynebacterium diphtheriae, Neisseria meningitidis, Neisseria gonorrhoeae and Clostridium* species. *Also*, FUSIX is active in terms of clinical against the strains of *Streptococci, Haemophilus, Moraxella and Corynebacteria*.

5.2 Pharmacokinetic properties
One drop fusidic acid administration remains in sufficient concentrations in lachrymal fluid and aqueous humor fluid for at least 12 hours. Following one drop fusidic acid administration at 1, 3, 6 and 12 hours, the mean concentration of fusidic acid in lachrymal fluid is respectively; 15.7 mg/L, 15.2 mg/L, 10.5 mg/L and 5.6 mg/L. Fusidic acid penetrates into intact as well as operated cornea epithelium. After one drop of fusidic acid, 0.3 mg/L fusidic acid mean concentration in aqueous humor is sustained at least for 12 hours. This level is higher than the MIC level for most of the associated bacteria (for *Staphylococcus aureus* MIC_{90} value = 0.06 mg/L).

5.3 Preclinical safety data
Not reported.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium chloride
Mannitol
Disodium edetate
Carbomer (974 P)
Sodium hydroxide
Deionized water

6.2 Incompatibilities
No incompatibility has been reported.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 25°C at room temperature.
Once the tube is opened, this product should be used in 15 days.

6.5 Nature and contents of container
It is presented in 5 g laminated high density polyethylene foldable tube with high density polyethylene application tip and cap.

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local disposal regulations.

7. MARKETING AUTHORIZATION HOLDER
DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No:1
34303 Küçükçekmece – ISTANBUL/TURKEY

8. MARKETING AUTHORIZATION NUMBER(S)

2014/917

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization : 22.12.2014
Date of latest renewal :

10. DATE OF REVISION OF THE TEXT

28.02.2025