# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

OPTICIN 1% w/w Viscous Eye Drops
Sterile

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains 10.18 mg fusidic acid hemihydrate equal to 10 mg fusidic acid.

## 3. PHARMACEUTICAL FORM

Viscous eye drops.
White or off-white homogenous viscous solution in laminate (polyfoil) tubes with high density polyethylene tip and cap.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Bacterial eye infections caused by susceptible organisms in conjunctivitis, blepharitis, sty, keratitis, dacryocystitis and in connection with removal of foreign bodies.

### 4.2 Posology and method of administration

**Posology/frequency and duration of administration**
One drop to be instilled into the eye twice daily. Treatment should be continued for at least two days after the eye appears normal.

**Method of administration**
For ophthalmic use only.

**Instructions for proper use**
Always use OPTICIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This medicine is only for use in your eyes. Do not swallow the drops. Do not put the drops inside your body or in your ears.

Always wash your hands before using OPTICIN. Do not use if the cap seal on the tube is broken. This diagram will help show how to use your medicine. It may be useful to look in a mirror.

Only take the cap off the tube when you are ready to use the medicine. It is important the tip of the tube does not touch your eye.

Tilt your head back. Pull your lower eyelid down gently. Hold the tube over your eye and look up. Squeeze one drop into your lower eyelid. The drop will come out as a thick drop. It will become more liquid in your eye and you should still see clearly.

After using your medicine you may see a white powder around your eye. This can happen when the drops dry out. It is quite normal and is nothing to worry about. You can wipe the powder off with cotton wool.

If the medicine is for a child, you can put the drops in their eye while they are asleep or lying down if it is easier.

Your doctor will tell you how many drops to use, or to give to your child. To remind you to use your medicine it may help to use it when you do another regular action, such as brushing your teeth.

**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**
Contact lenses should not be worn/used when OPTICIN 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 and recurrent use may increase the risk of developing antibiotic resistance.

OPTICIN 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 OPTICIN is negligible**.**

**4.6 Fertility, pregnancy and lactation**

**Pregnancy**
No effects during pregnancy are anticipated, since systemic exposure to OPTICIN is negligible. OPTICIN 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. OPTICIN can be used during breast-feeding.

**Fertility**
There are no clinical studies with OPTICIN regarding fertility. No effects on women of childbearing potential are anticipated, since systemic exposure to OPTICIN is negligible.

**4.7 Effects on ability to drive and use machines**
OPTICIN has no or negligible influence on the ability to drive or use machines. OPTICIN 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 fusidic acid 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<br>Angioedema |
| | Rare | Urticaria |
| General disorders and administration site conditions | Common | Application site pain (including eye burning and eye stinging)<br>Application site pruritus<br>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 in accordance with local requirements.

### 4.9 Overdose
The total quantity of fusidic acid in one 5 g tube of OPTICIN 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 sustained release formulation of fusidic acid eye drops ensures a prolonged contact with the conjunctival sac. Twice daily application pro vides sufficient fusidic acid concentrations in all relevant tissues of the eye. Fusidic acid penetrates well into the aqueous humour.

### 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
Purified water

### 6.2 Incompatibilities
No incompatibility has been reported.

### 6.3 Shelf life
24 months

### 6.4 Special precautions for storage
Store below 30°C.
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 laminate (polyfoil) tube with high density polyethylene 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. MANUFACTURER**
DEVA HOLDING ANONIM SIRKETI
Çerkezköy Organize Sanayi Bölgesi
Karaağaç Mah. Atatürk Cad., No: 32
Kapaklı - TEKIRDAĞ/TÜRKİYE

**8. PRODUCT REGISTRATION HOLDER (PRH)**
InstaMed Asia Sdn Bhd.
108, Block E, Phileo Damansara 1 No.9, Jalan 16/11, Petaling Jaya, 46350 Petaling Jaya, Selnagor, Malaysia

**9. DATE OF REVISION OF THE TEXT**

13.12.2024

Times New Roman with 12 font size were used in SPC.