

## Package leaflet INFORMATION FOR THE USER

### Fucithalmic® 10 mg/g eye drops, suspension

Fusidic acid

**Read all of this leaflet carefully because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice adverse effects, consult your doctor or pharmacist even if the adverse effects you experienced are not mentioned in this package leaflet.

#### **In this leaflet:**

1. What Fucithalmic® is and what it is used for
2. What you should know before you use Fucithalmic® eye drops
3. How to use Fucithalmic® eye drops
4. Possible side effects
5. How to store Fucithalmic® eye drops
6. Contents of the package and other information

#### **1. What fucithalmic® is and what it is used for**

Fusidic acid is an antibiotic that kills bacteria. Fucithalmic® eye drops are used to treat eye infections caused by bacteria susceptible to fusidic acid. If your doctor has given other instructions for using the drug, you should follow them.

#### **2. What you should know before you use Fucithalmic® eye drops.**

##### **Don't use Fucithalmic® eye drops:**

- if you are allergic (hypersensitive) to fusidic acid, sodium fusidate or any other excipients (listed in section 6).

##### **Warnings and precautions**

You should consult with your doctor or pharmacist before using Fucithalmic® eye drops.

Prolonged or repeated use of Fucithalmic® may increase the risk of developing antibiotic resistance.

Fucithalmic® eye drops must not be used with contact lenses because the eye drops contain microcrystals. Microcrystalline fusidic acid may cause scratches in the contact lens or cornea. Contact lenses may be worn 12 hours after discontinuation of treatment.

#### **Other medicinal products and Fucithalmic® eye drops**

You should tell your doctor or pharmacist if you are using or recently have used other drugs, or may have to use other medicines.

### **Pregnancy, lactation and fertility**

If you are pregnant or lactating, suspect that you may be pregnant or planning to become pregnant, consult with your doctor or pharmacist before using this medicine.

Since systemic absorption of the medicinal product from the eye is negligible, the product can be used during pregnancy.

No effect is anticipated concerning fertility.

### **Driving and using machines**

Fucithalmic<sup>®</sup> drops may cause transient blurring of vision after application. When the vision has returned to normal, Fucithalmic<sup>®</sup> drops do not have an adverse effect on the ability to drive and using machines.

## **3. How to use Fucithalmic<sup>®</sup> eye drops**

Always use this medicine exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

### **Dosage**

1 drop twice a day. Initially, more frequent dosage may be used; in addition, the eye should be cleaned frequently. For prevention of recurrence, treatment should be continued for at least 2 days after the symptoms have subsided.

### **Instructions for use**

Pull your lower eye lid as shown in the figure. Apply one drop Fucithalmic<sup>®</sup> eye drops on the conjunctiva without touching the eye or its surroundings.

Fucithalmic<sup>®</sup> eye drops are viscose but in contact with the tear fluid they turn clear and liquid.

### **If you use more Fucithalmic<sup>®</sup> eye drops than you should**

Not applicable.

### **If you forget to take Fucithalmic<sup>®</sup> eye drops**

Do not take a double dose to make up for a forgotten individual dose.

## **4. Possible side effects**

Like all medicines, this medicine may cause side effects, although not everybody gets them.

Common (more than in one patient in 100): Burning, stinging, itching, and irritation in the eyes, application site pain, transient blurring of vision after application.

Uncommon (less than in one patient in 100): Hypersensitivity, watery eyes, eyelid oedema.

Rare (less than in one patient in 1000): urticaria, worsening of conjunctivitis, angio-oedema (swelling elsewhere than around the eyes, including the face, lips, tongue, or throat), rash.

### Side-effects in children

Side-effects in children are anticipated to be the similar as in adults.

If you notice adverse effects, consult your doctor or pharmacist even if the adverse effects you experienced are not mentioned in this package leaflet.

### **5. How to store Fucithalmic® eye drops**

Store below 25°C.

Keep out of reach and sight of children.

Do not use the medicine after the expiration date (abbr. Käyt.viim.) printed on the package. The expiration date stands for the last day of the month.

The shelf-life of an opened package is 28 days.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

### **6. Contents of the package and other information**

#### **What Fucithalmic® eye drops contain**

- The active ingredient is fusidic acid 10 mg/g (1%)
- Other ingredients are benzalkonium chloride, carbomer, mannitol, sodium hydroxide, disodium edetate, water for injections.

#### **Description of the medicine and package size**

White or yellowish viscose eye drops, suspension, 5 mg tube.

#### **Marketing Authorisation Holder:**

Amdipharm Limited

Temple Chambers

3 Burlington Road

Dublin 4

Ireland

#### **Manufactured by:**

LEO Pharma A/S, Industriparken 55, 2750, Ballerup, Denmark

#### **This leaflet was last approved on**

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