

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Fucithalmic® 10 mg/g eye drops, suspension** fusidic acid

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Fucithalmic® is and what it is used for
2. Before you use Fucithalmic®
3. How to use Fucithalmic®
4. Possible side effects
5. How to store Fucithalmic®
6. Further information

#### **1. WHAT FUCITHALMIC® IS AND WHAT IT IS USED FOR**

Fucithalmic® belongs to a group of medicines called antibiotics. It works by killing the bacteria causing the eye infection. The sustained-release formulation of Fucithalmic® ensures a prolonged contact with the conjunctival sac. A twice-daily application provides sufficient concentrations in all relevant tissues of the eye. Fucithalmic® penetrates well into the aqueous humour.

##### **Indications of Fucithalmic®**

Bacterial eye infections caused by susceptible organisms in conjunctivitis (inflammation of the conjunctiva).

#### **2. BEFORE YOU USE FUCITHALMIC®**

##### **Do not use Fucithalmic®**

- If you are allergic (hypersensitive) to fusidic acid, or any of the other ingredients of Fucithalmic®

##### **Take special care while using Fucithalmic®**

Contact lenses should not be worn when Fucithalmic® is used since the suspension contains microcrystals. Contact lenses can be used 12 hours after treatment course has ended.

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

Ask your doctor or pharmacist for advice before using Fucithalmic®:

- If are pregnant or think you are pregnant
- If you are breast-feeding.

##### **Driving and using machines**

Following application of your medicine a brief blurring of vision may occur. Do not drive or use machinery until your vision is clear.

**Important information about some of the ingredients of Fucithalmic®**

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

**3. HOW TO USE FUCITHALMIC®**

Always use Fucithalmic® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Dosage**

One drop to be instilled into the eye twice daily. Treatment should be continued for at least two days after the eye appears normal.

If you have any further questions about using this medicine, please ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Fucithalmic® can cause side effects, although not everybody gets them.

The most frequently reported adverse drug reactions are various application site reactions such as pain, pruritus, discomfort/irritation/ in/around the eyes or transient blurring of vision. Urticaria, rash and allergic reactions have been reported.

**Common side effects (affects less than 1 in 10 people)**

- Transient blurring of vision
- Application site pain (including eye burning and eye stinging)
- Application site pruritus
- Application site discomfort/irritation

**Uncommon side effects (affects less than 1 in 100 people)**

- Allergic reaction
- Eyelid oedema
- Lacrimation increased
- Swelling of the face, tongue and/or larynx
- Rash

**Rare side effects (affects less than 1 in 1000 people)**

- Conjunctivitis aggravated
- Urticaria

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE FUCITHALMIC®**

Keep out of the reach and sight of children

Do not store above 30° C

Do not use after the expiry date indicated on the package.

Shelf life after first opening: 28 days.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away medicines you do not need anymore. If you do this you will help protect environment.

## **6. FURTHER INFORMATION**

### **What Fucithalmic® contains**

Fucithalmic® is a sterile 1% aqueous sustained-release formulation of fusidic acid, preserved with benzalkonium chloride.

One gram of suspension contains 10 mg fusidic acid (as hemihydrate).

### **The active substance is:**

Fusidic acid

One gram of suspension contains 10 mg fusidic acid (as hemihydrate).

### **List of excipients**

Benzalkonium chloride

Disodium edentate

Mannitol

Carbomer

Sodium hydroxide

Water for injection

### **What Fucithalmic® looks like and the contents of the pack**

5g tubes.

### **Marketing Authorization Holder**

Amdipharm Limited

Temple Chambers

3 Burlington Road

Dublin 4

Ireland

### **Manufacturer**

LEO Laboratories Ltd.

285 Cashel Road

Dublin 12

Ireland

### **Date of last revision of the text**