


ARTWORK

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LEO Pharma A/S
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Industriparken 55 – DK-2750 – Ballerup

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Subject			Date	Date	Date
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Preparation Strength	Paper	Web	Supplier / Place of production
Fucithalmic® Unit Dose	45 g white	BB	Quickly Tryk 
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280 mm
145 mm
80 mm

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.

How much Fucithalmic® to use
Your doctor will tell you how many drops to use, or to give to your child.

You should use your medicine twice each day. To remind you to use your medicine it may help to use it when you do another regular action, such as brushing your teeth.

Adults, the elderly and children
The usual dose is one drop twice each day, in the morning and in the evening.

Taking all the course of Fucithalmic®
It is very important to use all the medicine that your doctor has told you to use. You must use your medicine for at least 48 hours after you feel better and your eye looks normal. You must do this because otherwise your eye infection may come back.

If you forget to use Fucithalmic®
If you forget to use your medicine, use it as soon as you remember. Then next use your medicine at the usual time.

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

4. Possible side effects
Like all medicines, Fucithalmic® can cause side effects, although not everyone gets them.

In clinical trials, 11 out of every 100 people got a side effect.
The most frequent side-effects were pain (stinging and burning), itching and irritation or discomfort in or around the eye which occurred in approximately 9 out of every 100 patients, followed by blurred vision which occurred in 1 in every 100 patients.
Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing have been reported by a few patients.

Important side effects to look out for:

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction. This is uncommon (probably affects up to 1 in 100 people):

- You have difficulty breathing.
- Your lips and mouth start to tingle and swell.
- Your face, especially around your eyes, or eyelids, or throat swells.
- Your skin develops a severe rash.
- You have burning or stinging in your eye that does not go away.

Other possible side effects, which are less serious, can also occur:

Common (probably affects up to 1 in 10 people)
Eye problems

- Short term blurring of your sight.
- Pain, itching, discomfort or irritation for a short time after putting the drops in your eye.

Uncommon (probably affects up to 1 in 100 people)

- Watery eyes
- Swelling of the eyelids
- Rash

Rare (probably affects up to 1 in 1000 people)

- Your eye infection may get worse
- Hives

If you notice the above or any other changes in your health while using this medicine, tell your doctor.

If you get any side-effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Fucithalmic®

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month. Any remaining dropper units should be discarded one month after first opening the foil pack.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and further information

What Fucithalmic® contains

- The active ingredient is fusidic acid. Each 0.2 g unit dose contains 2 mg of fusidic acid.
- The other ingredients are sodium acetate, mannitol, carbomer, sodium hydroxide and water for injections.

What Fucithalmic® looks like and contents of the pack
Fucithalmic® is a white to off-white, slightly thick liquid.

Fucithalmic® comes in a unit dose containing 0.2 g. These are supplied in a foil pack each containing 12 plastic unit dose droppers.

Marketing Authorisation Holder and Manufacturer
LEO Laboratories Limited, Cashel Road, Dublin 12.

For further information about this product, contact the local representative of the marketing authorisation holder:
Medical Division, LEO Pharma, Dublin 12
Telephone: +353 1 490 8924
Email: medical-info.ie@leo-pharma.com

Date leaflet last approved: XX-YYY

® Registered Trade Mark

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Item-number:
See details below.

