



AMDIPHARM

Patient Information Leaflet

Fucithalmic® Viscous eye-drops, 10mg/g

Fusidic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet

1. What Fucithalmic® Viscous eye-drops are and what they are used for.
2. What you need to know before you use Fucithalmic® Viscous eye-drops.
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1. What Fucithalmic® Viscous eye-drops are and what they are used for

Fucithalmic® is active against Staphylococci, Streptococci, Neisseria, Haemophilus, Moraxella and Corynebacteria.

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.

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

2. What you need to know before you use Fucithalmic® Viscous eye-drops

Do not use Fucithalmic® Viscous eye-drops

if you are allergic to fusidic acid or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Do not use Fucithalmic® Viscous eye-drops for a long time as the bacteria may no longer be killed by the antibiotic.
- Contact lenses should not be worn when Fucithalmic® viscous eye-drops are used.

Talk to your doctor or pharmacist before using Fucithalmic® viscous eye-drops.

Other medicines and Fucithalmic® Viscous eye-drops

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Fucithalmic® Viscous eye-drops contains Benzalkonium chloride

- Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
- Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Fucithalmic® Viscous eye-drops

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Fucithalmic® has a very low allergenic potential.

Side effects listed below have been reported in the following frequencies:

Common: may affect up to 1 in 10 people

- Eye burning
- Eye stinging
- Blurring of vision

Uncommon: may affect up to 1 in 100 people

- Watery eyes

Rare: may affect up to 1 in 1,000 people

- Swelling of the eyelids
- Allergic reaction

Not known: frequency cannot be estimated from the available data

- Itching
- Swelling or puffiness around the eye area
- Rash
- Hives
- Swelling under the skin

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

5. How to store Fucithalmic® viscous eye-drops

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Keep cap tightly closed.

Discard 28 days after opening.

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

6. Further information

a. What Fucithalmic® viscous eye-drops contains

- Fucithalmic® is a sterile 1% aqueous sustained-release formulation of fusidic acid.
- Fucithalmic® Viscous eye-drops contains 10 milligrams of fusidic acid in each gram.
- The other ingredients are benzalkonium chloride, disodium edetate, mannitol, carbomer, sodium hydroxide and water for injections.

b. What Fucithalmic® viscous eye-drops looks like and contents of the pack

Fucithalmic® viscous eye-drops is a white to off-white, viscous suspension. Fusidic acid Eye Drops comes in tubes of 5 g and 3g.

c. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm Limited

Temple Chambers, 3 Burlington Road, Dublin 4, Ireland

Manufacturer:

LEO Laboratories Ltd.

285 Cashel Road, Crumlin, Dublin 12, Ireland

d. This leaflet was last revised in June 2019

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e. To report any side effect

• Saudi Arabia:

The National Pharmacovigilance Centre (NPC):
Fax: +966-11-205-7662
Call NPC at +966-11-2038222, Ext 2317-2356-2340
SFDA Call Center: 19999
E-mail: npc.drug@sfd.gov.sa
Website: <https://ade.sfd.gov.sa/>

• Other GCC states

- Please contact relevant competent authority

f. Council of Arab Health Ministers

The following statements issued by the Council of Arab Health Ministers should be printed in the PIL.

THIS IS A MEDICINE

- Medicine is a product, but not like other products.
 - Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the Doctor's prescription, the method of use and the instructions of the Pharmacist who sold you the medicine.
- The Doctor and Pharmacist are experts in medicines, their benefits and their risks.
- Do not by yourself interrupt the period of treatment prescribed to you.
 - Do not repeat the same medicine and do not increase doses without consulting your Doctor.

Council of Arab Health Ministers
Union of Arab Pharmacists