

Package leaflet: Information for the user

Fucithalmic[®] 10 mg/g Viscous Eye Drops, Suspension 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.

The name of your medicine is Fucithalmic[®] 10 mg/g Viscous Eye Drops, Suspension but it will be referred to as Fucithalmic in the rest of the leaflet.

What is in this leaflet:

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

1. What Fucithalmic is and what it is used for

Fucithalmic belongs to a group of medicines called antibiotics.

The antibiotic in this product is called fusidic acid.

It works by killing germs (bacteria) that cause infections.

Fucithalmic is an eye drop medicine used to treat eye infections caused by germs (bacterial conjunctivitis).

2.What you need to know before you use Fucithalmic

Do not use Fucithalmic:

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

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before using Fucithalmic

- Do not wear any type of contact lenses while using this medicine.
- Do not use Fucithalmic for a long time as the bacteria may no longer be killed by the antibiotic.
- Always use Fucithalmic for the amount of time your doctor has instructed you to use it for.

Other medicines and Fucithalmic:

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines which you have bought without a prescription, or herbal medicines.

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.

- No effects are anticipated during pregnancy, since systemic exposure to Fucithalmic is insignificant. Fucithalmic can be used during pregnancy.
- No effects on the breast-feeding newborn/infant are anticipated, as the systemic exposure of the breast-feeding woman to fusidic acid is insignificant. Fucithalmic can be used during breast-feeding.
- No effects on women of potential childbearing are anticipated, since systemic exposure to Fucithalmic is insignificant.

Driving and using machines

Usually your medicine will have very little effect on your ability to drive or use machines. Sometimes it can cause your sight to be blurred for a short time after use. The drop will become liquid in your eye and you should still see clearly.

Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Fucithalamic contains Benzalkonium chloride:

This medicine contains 0.33 mg benzalkonium chloride in each 3 g tube which is equivalent to 0.11 mg/g.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Contact lenses should not be used during treatment with Fucithalamic, see section "Warnings and Precautions"

Benzalkonium chloride may 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

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. How to use Fucithalamic

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

How to administer Fucithalamic

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 Fucithalamic.

This picture 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, as shown in the picture.

Squeeze one drop into your lower eyelid or if both eyes are infected, put one drop in both eyes. 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.

Use in children:

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 recommended 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 use more Fucithalmic than you should

If you accidentally apply too many drops in the eye(s) or a small quantity of the drops are accidentally swallowed, it is unlikely to cause any harm. If a larger quantity of the drops are accidentally swallowed or you are worried contact your doctor, pharmacist or A+E department for advice.

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 stop using Fucithalmic

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Uncommon (may affect 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 (may affect 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 (may affect up to 1 in 100 people)

- Watery eyes
- Swelling of the eyelids

- Rash.

Rare (may affect 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

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.
- Do not keep the tube for more than 28 days after you first open it.
- Store below 25°C. Keep the tube tightly closed.

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. Contents of the pack and other information

What Fucithalmic contains

- The active substance is fusidic acid.

Fucithalmic contains 10 milligrams of fusidic acid in each gram of drops.

- The other ingredients are benzalkonium chloride, disodium edetate, mannitol, carbomer, sodium hydroxide and water for injections.

You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What Fucithalmic looks like and contents of the pack

Fucithalmic is a white to off-white, slightly thick liquid.

Fucithalmic comes in 3 g tubes.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amdipharm Limited
Temple Chambers, 3 Burlington Road
Dublin 4, Ireland

Manufacturer:

CENEXI HSC
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