PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucithalmic[®] Viscous Eye Drops Fusidic Acid 1% Viscous Eye Drops (fusidic acid)

Your medicine is available using one of the above names but will be referred to as Fucithalmic throughout this leaflet.

Please read all of this leaflet carefully before you start taking 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 become serious, or 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 antiinfectives. It is a type of antibiotic.

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

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

2. Before you use Fucithalmic

Do not use Fucithalmic

• If you are allergic (hypersensitive) to fusidic acid, or any of the other ingredients in your medicine. You can find a list of these ingredients in section 6 of this leaflet.

Take special care with Fucithalmic

Do not wear any type of contact lenses whilst using this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before using Fucithalmic:

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

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

Important information about some of the ingredients of Fucithalmic

Fucithalmic contains:

 Benzalkonium chloride. This is a preservative. It may cause eye irritation.

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

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.

How to use Fucithalmic

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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 Fucithalmic. Do not use if the cap seal on the tube is broken.

This diagram 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.

Squeeze one drop into your lower eyelid. 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.

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.

What to do 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 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 everybody gets them.

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:

- You have difficulty breathing
- Your face, especially around your eyes or your eyelids, or throat swell
- Your skin develops a severe rash
- You have burning or stinging in your eye that does not go away

Other possible side effects:

Common side effects (probably affect less than 1 in 10 people)

- Burning, stinging, discomfort, smarting, irritation, itching, soreness or dryness in the eye being treated.
- Blurring of vision in the eye being treated.

Uncommon side effects (probably affect less than 1 in 100 people)

Watery eyes or crying on application

Side effects where the number of people affected is not known:

- Itching
- Rash
- Hives
- Conjunctivitis may get worse

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

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. How to store Fucithalmic

- Keep the tube in a safe place out of the sight and reach of children.
- Store below 25°C.
- Sterile only until opened. Discard any unused solution 4 weeks after opening.

- The eye drops should not be used after the expiry date printed on both the carton and label on the tube. The expiry date is the last day of that month.
- Any solution remaining 28 days after first opening the tube should be discarded or taken to your pharmacist for safe disposal.
- If the drops become discoloured or show any other signs of deterioration, you should seek the advice of a pharmacist.
- Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

6. Further information

What Fucithalmic contains

- The name of your viscous eye drops is Fucithalmic Viscous Eye Drops / Fusidic Acid 1% Viscous Eye Drops. Each gram of eye drop solution contains 10mg of fusidic acid hemihydrate as the active ingredient.
- Fucithalmic Eye Drops / Fusidic Acid 1% Viscous Eye Drops also contains the following: Benzalkonium chloride, disodium edetate, mannitol, carbomer 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 packaged as a carton containing one 5g tube and is ONLY for use in the eyes.

Manufacturer

Manufactured by: Leo Laboratories Limited, 285 Cashel Road, Dublin 12, Ireland.

Procured from within the EU and repackaged by the Licence Holder: Doncaster Pharmaceuticals Group Limited, Kirk Sandall Industrial Estate, Kirk Sandall, Doncaster, DN3 1QR.

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