Package leaflet: Information for the user

Fusidic Acid 1% w/w Viscous Eye Drops

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 Fusidic Acid 1% w/w Viscous Eye Drops but it will be referred to as Fusidic acid in the rest of the leaflet.

What is in this leaflet:

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

1. WHAT FUSIDIC ACID IS AND WHAT IT IS USED FOR

Fusidic acid belongs to a group of medicines called anti-infectives. It is a type of antibiotic.

Fusidic acid works by killing germs (bacteria) that cause infections.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FUSIDIC ACID

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

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

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

Fusidic acid contains Benzalkonium chloride
This medicine contains 0.55mg benzalkonium chloride in each 5g tube which is equivalent to 0.11mg/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 Fusidic acid, see section "Warnings and Precautions".

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.

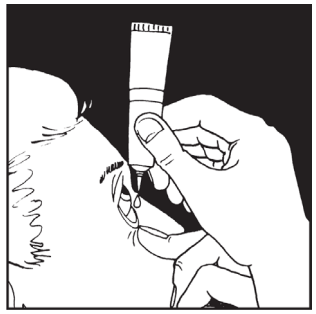
Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. HOW TO USE FUSIDIC ACID

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 Fusidic acid
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 Fusidic acid. 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.

Use in children
If this 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 Fusidic acid 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 Fusidic acid
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 Fusidic acid 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 Fusidic acid
If you forget to use your medicine, use it as soon as you remember. Then next use your medicine at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using Fusidic acid
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.

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 (may affect up to 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 (may affect up to 1 in 100 people)
- Watery eyes or crying on application
- Swelling of the eyelids
- Rash.

Rare (may affect up to 1 in 1000 people)
- Hives
- Your eye infection may get worse.

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 or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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

5. HOW TO STORE FUSIDIC ACID
- Keep the tube in a safe place out of the sight and reach of children.
- Do not store above 25°C.
- Keep the tube tightly closed. The tube should be discarded one month after first 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.
- If the drops become discoloured or show any other signs of deterioration, you should seek the advice of a pharmacist.
- 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 Fusidic Acid contains
- Fusidic Acid contains 1% w/w of fusidic acid.
- Fusidic Acid also contains the following inactive ingredients: 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 Fusidic Acid looks like and contents of the pack
Fusidic Acid is a white to off-white viscous sterile solution and is ONLY for use in the eyes.

Fusidic Acid comes in 5 gram tubes.

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

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0100 POM

Leaflet revision and issue date (Ref): 31.08.22

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)
Please be ready to give the following information:
Product name:
Fusidic Acid 1% w/w Viscous Eye Drops
Reference No: 56830/0100