

# Fucidin® 250 mg/5 ml Oral Suspension

fusidic acid

**Read all of this leaflet carefully before you start taking 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Fucidin® 250 mg/5 ml Oral Suspension will be called Fucidin Suspension.

## What is in this leaflet

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

### 1. What Fucidin® Suspension is and what it is used for

Fucidin Suspension contains fusidic acid. It is a type of antibiotic.

Fucidin Suspension works by killing germs (bacteria) that cause infections. Fucidin Suspension is used to treat infections such as those caused by a bacteria called *Staphylococcus*.

### 2. What you need to know before you take Fucidin® Suspension

#### Do not take Fucidin Suspension:

- If you are allergic to fusidic acid or any of the other ingredients in this medicine (listed in section 6).
- If you are taking statins, medicines to lower blood cholesterol.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Fucidin Suspension if:

- You are taking statins (medicines to lower blood cholesterol).
- You have problems with your liver or if you have recently been jaundiced (skin and whites of eyes appear yellow).
- You have a blockage or a problem with your bile duct, e.g. gallstones.
- You are taking some medicines called HIV-Protease Inhibitors used to treat the HIV virus.

When you are taking Fucidin Suspension your doctor may take regular blood tests if you are taking other medicines which affect the liver.

If you are concerned that your treatment is not as effective as it should be, tell your doctor. As with any antibiotic treatment, long term or repeated use may increase the risk of developing antibiotic resistance.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

A few cases have been reported of severe skin reactions, which may develop into potentially life-threatening skin reactions if they are not treated. Contact your doctor immediately if you experience any symptoms of these reactions anytime within 8 weeks after first use of Fucidin, even if you have stopped taking Fucidin. Symptoms of skin reactions include skin rashes or redness, including widespread rash with blisters and peeling skin particularly occurring around the mouth, nose, eyes and genitals, fever, stinging eyes and discomfort on swallowing.

#### Other medicines and Fucidin Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might have taken any other medicines. This includes any medicines which you have bought without a prescription and herbal medicines. Fucidin Suspension may interact with other medicines, which could mean your dose of these medicines may need to be changed.

- Do not take statins (medicines to lower blood cholesterol) while using this medicine.

You must tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to lower blood cholesterol, such as statins. Taking Fucidin Suspension and statins at the same time may lead to muscle weakness, tenderness or pain. Also see section 4 of this leaflet.

- Oral anti-coagulants (medicines to “thin” your blood). You may be likely to bleed more easily. Your doctor may need to change your dose.
- Medicines used to treat HIV (e.g. ritonavir or saquinavir).

#### 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.

- Fucidin Suspension should not be used during pregnancy unless you are told to do so by your doctor.
- If you are breast-feeding or planning to breast-feed, ask your doctor or pharmacist for advice before taking this medicine.

Tell your doctor if you become pregnant while using this medicine.

#### Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

#### Fucidin Suspension contains

- Liquid Glucose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The suspension contains 1.25 grams (g) glucose in each 5 millilitres (ml). This should be taken into account in patients with diabetes mellitus.
- Sorbitol (E420) (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The suspension contains 500 milligrams (mg) sorbitol in each 5 ml.
- Orange flavour (which contains sucrose, a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Sodium. The suspension contains 1.6 mg sodium per ml. You should take this into consideration if you are on a controlled sodium diet.

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

### 3. How to take Fucidin® Suspension

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

#### How much Fucidin Suspension to take

Your doctor will tell you how much Fucidin Suspension to take or to give to your child and how many times each day to take it.

You should take the medicine at equally spaced times in the day.

For oral administration. Shake well before use.

The recommended dose is:

#### Adults and the Elderly

30 - 40 ml each day. This dose will be divided into 3 equal doses.

#### Children

0.4 ml/kg – 1 ml/kg each day. This will be divided into 3 equal doses.

#### If you take more Fucidin Suspension than you should

You may experience a sudden onset of vomiting, diarrhoea, stomach pain, heartburn and nausea (feeling sick) if you take too much suspension.

Tell your doctor straight away if you have taken more suspension than you should. You may need to stop taking this medicine.

**If you forget to take Fucidin Suspension**

If you forget to take the suspension at the right time, take it as soon as you remember. Then next take this medicine at the usual time.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Fucidin Suspension**

It is very important to take all the medicine that your doctor has told you to take. You must finish this medicine even if you feel better. You must do this because otherwise your infection may come back.

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

**4. Possible side effects**

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

**Important serious side effects to look out for:**

**Tell your doctor or pharmacist immediately if any of the following happen. You may need to stop your treatment:**

- You have difficulty breathing
- Your face or throat swell
- Your skin develops a severe rash.

**Tell your doctor or pharmacist immediately if any of the following happen. You may be developing a condition called rhabdomyolysis:**

- You develop muscle weakness
- You develop muscle pain
- You develop muscle tenderness.

**Problems with your liver or kidneys.**

**Tell your doctor or pharmacist immediately if any of the following happen:**

- Your skin or the whites of your eyes appear yellow
- You are not passing water.

**The level of some cells in your blood may change. Tell your doctor or pharmacist immediately if any of the following happen:**

- You develop any unexplained bruising or bleeding
- You develop persistent or repeated mouth ulcers, sore throats or other infections.

**Tell your doctor or pharmacist immediately if the following happens:**

- You develop a skin rash with pus filled pimples or blisters and fever. You may be experiencing a condition known as acute generalised exanthematous pustulosis (AGEP) and your doctor will tell you if you should stop taking Fucidin Suspension.

**A few cases have been reported of severe skin reactions after taking Fucidin, which may develop into potentially life-threatening skin reactions if they are not treated. Tell your doctor or pharmacist immediately if you experience any of the following symptoms. You may experience influenza and flu-like symptoms such as fever, headache and body ache before these skin reactions appear:**

- Skin rashes or redness, including widespread rash with blisters and peeling skin particularly around the mouth, throat, nose, eyes and genitals (Stevens-Johnson syndrome)
- Extensive peeling of the skin covering more than 30% area of the body surface (Toxic epidermal necrolysis)
- Extensive rashes involving the liver, blood and any other organ of the body (Drug Reaction with Eosinophilia and Systemic Symptoms, also known as DRESS syndrome).

**The following less serious side effects have also been reported. If any of them last a long time or cause problems, you should tell your doctor or pharmacist as soon as possible:**

**Common (may affect up to 1 in 10 people)**

- Vomiting
- Stomach pain or discomfort
- Heartburn
- Nausea
- Fatigue
- Diarrhoea

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

- Drowsiness
- Headache
- Pale stools
- Dark urine
- Upper right hand side stomach pain
- Loss of appetite
- Itchy rash
- Itching
- Rash
- Skin redness

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earsfort Terrace, IRL-Dublin 2; Tel +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie) By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Fucidin® Suspension**

- Keep this medicine out of the sight and reach of children.
- Do not use Fucidin Suspension after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.
- Discard any unused suspension one month after first opening.

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 to protect the environment.

**6. Contents of the pack and other information****What Fucidin Suspension contains**

- The active substance is fusidic acid.
- Fucidin Suspension contains 250 mg of fusidic acid in every 5 ml of suspension.
- The other ingredients are banana flavour, citric acid monohydrate, disodium phosphate dihydrate (E339), glucose liquid, hyetellose, acesulfame potassium, orange dry flavour (contains sucrose), sodium benzoate (E211), sorbitol (E420), methylcellulose and purified water.

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

**What Fucidin Suspension looks like and contents of the pack**

Fucidin Suspension is a cream coloured suspension with odour of banana. Fucidin Suspension comes in a 50 ml amber glass bottle with a measuring cup.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: LEO Laboratories Limited, Cashel Road, Dublin 12.  
Manufacturer: LEO Pharma A/S, Industriparken 55, DK – 2750 Ballerup, Denmark.

**For further information about this product, contact the local representative of the marketing authorisation holder:**

Medical Division  
LEO Laboratories Ltd  
Dublin 12, Ireland  
Telephone: +353 1 490 8924  
E-mail: [medical-info.ie@leo-pharma.com](mailto:medical-info.ie@leo-pharma.com)

**This leaflet was last revised in April 2017.**

® Registered Trade Mark



**LEO**

032694-XX