

PACKAGE LEAFLET: INFORMATION FOR THE USER

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:

- Infections of the skin and wounds
- Infections of the blood such as septicaemia
- Infections of the bone and heart tissue
- Infections of the lungs such as pneumonia
- Infections connected with the condition cystic fibrosis.

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 of this medicine (listed in section 6).

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.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of Fucidin Suspension.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

The highest risk for occurrence of serious skin reactions is within 8 weeks of treatment. If you develop a serious rash or another of these skin symptoms, stop taking Fucidin Suspension and contact your doctor or seek medical attention immediately.

Other medicines and Fucidin Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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). This is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- 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. This is the equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.
- This medicine contains up to 7.5 µg benzyl alcohol per ml. The maximum dose is equivalent to 94 to 375 µg/day. Benzyl alcohol may cause allergic reactions.

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

15 ml, 3 times each day.

Children

- Under 1 year: 1 ml/kg bodyweight each day. This dose will be divided into 3 equal doses.
- Between 1-5 years: 5 ml, 3 times each day.
- Between 5-12 years: 10 ml, 3 times each day.

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 using 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.

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. The frequency of these side effects is not known (cannot be estimated from the available data):

- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central

blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. Stop using Fucidin Suspension if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

- **Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome). Stop using Fucidin Suspension if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.**
- **A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Fucidin Suspension if you develop these symptoms and contact your doctor or seek medical attention immediately.**

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
- Rash.

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

- Itching
- 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 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 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 within 28 days after first opening.
- This medicine does not require any special storage conditions.

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 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 acesulfame potassium, banana flavour, orange dry flavour (contains sucrose), citric acid, disodium phosphate dihydrate, glucose liquid, hydroxyethylcellulose, methylcellulose, sodium benzoate (E211), sorbitol (E420) and purified water.

You can find essential information about some of the ingredients in your medicine 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 or 90 ml amber glass bottle with a measuring cup.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: LEO Laboratories Limited, Maidenhead, Berkshire SL6 3UD, UK.

Manufacturer: LEO Pharma A/S, DK-2750 Ballerup, Denmark.

This leaflet was last revised in April 2023.

For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333.

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