

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucidin® 250 mg Tablets

sodium fusidate

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 Tablets will be called Fucidin Tablets.

What is in this leaflet

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

1. What Fucidin® Tablets are and what they are used for

Fucidin Tablets contain sodium fusidate. It is a type of antibiotic. Fucidin Tablets work by killing germs (bacteria) that cause infections. Fucidin Tablets are used to treat infections such as those caused by a bacteria called *Staphylococcus*.

2. What you need to know before you take Fucidin® Tablets

Do not take Fucidin Tablets:

- If you are allergic to sodium fusidate or any of the other ingredients of 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 Tablets 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 Tablets 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 any time 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 Tablets

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 Tablets 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 Tablets 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 Tablets 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 Tablets contain

- Lactose (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. Each tablet contains 71.9 milligrams (mg) of lactose per tablet.
- Sodium. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

3. How to take Fucidin® Tablets

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 many Fucidin Tablets to take

Your doctor will tell you how many tablets to take. Your doctor will tell you how many times each day to take your medicine.

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

For oral administration. Take the tablet(s) with a glass of water.

Do not take the tablets with a main meal.

Do not take the tablets for longer than your doctor has told you to.

The recommended dose is:

Adults and the Elderly

2 tablets, 3 times each day.

Children

20 to 50 mg per kg of bodyweight, taken in divided doses 3 times a day.

In severe infections, your doctor may increase the dose.

If you take more Fucidin Tablets than you should

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

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

If you forget to take Fucidin Tablets

If you forget to take the tablets at the right time, take them 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 Tablets

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 Tablets.

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 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
- Rash.

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 HPRAs 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 Fucidin Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use Fucidin Tablets after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.
- 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 any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fucidin Tablets contain

- The active substance is sodium fusidate. Fucidin Tablets contain 250 mg of sodium fusidate in each tablet.
- The other ingredients are microcrystalline cellulose, crospovidone, hypromellose, lactose monohydrate, magnesium stearate, colloidal anhydrous silica, all-rac- α -tocopherol, talc and titanium dioxide.

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

What Fucidin Tablets look like and contents of the pack

Fucidin Tablets are white to off-white greyish, marbled, oval film-coated tablets. Fucidin Tablets come in blister packs of 100 (10 x 10) tablets.

Marketing Authorisation Holder and Manufacturer.

Marketing Authorisation Holder: LEO Laboratories Limited, Cashel Road, Dublin 12.

Manufacturer: Laboratoires LEO S.A., 39 Routes de Chartres, F-28500, Vernouillet, France.

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