

FUCIDIN[®] TABLET

Sodium Fusidate (250mg)

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What Fucidin[®] tablet is used for

Fucidin[®] tablet contains sodium fusidate. It is a type of antibiotic.

Fucidin[®] tablet is indicated for the treatment of infections caused by susceptible organisms, especially staphylococci, for example:

- 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, a genetic disease that affects mucus and sweat glands, causing mucus to become thick and sticky.
- Inflammation of the endocardium, the inner layer of the heart.

How Fucidin[®] tablet works

Fucidin[®] tablet work by killing germs (bacteria) that cause infections.

Before you use Fucidin[®] tablet

- When you must not use it

Do not take Fucidin[®] tablet

- If you are allergic (hypersensitive) to fusidic acid or sodium fusidate.
- If you are allergic (hypersensitive) to any of the other ingredients in your

medicine. You can find a list of these ingredients in section: *Product Description* of this leaflet.

- If you are taking statins (medicines to lower blood cholesterol).

Pregnancy and lactation

Please ask your doctor or pharmacist for advice before taking Fucidin[®] tablet:

- 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.

- Before you start to use it

Take special care with Fucidin[®] tablet

Before you take Fucidin[®] tablet, tell your doctor:

- If you have problems with your liver
- If you have recently been jaundiced.

When you are taking Fucidin[®] Tablets your doctor may take regular blood tests in patients on high doses, with liver or bile problems, taking the medicine for a long time or taking other medicines that affect the liver.

- 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.

- 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:

- Other antibiotics, such as lincomycin and rifampicin.
- 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 to lower blood cholesterol, such as statins. This may lead to muscle weakness, tenderness or pain.
- Ritonavir or saquinavir, medicines used to treat HIV.
- Cyclosporin. This medicine is used to reduce the body's immune reactions.

How to use Fucidin[®] tablet

Always take Fucidin[®] tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

Your doctor will tell you how many tablets to take.

Take the tablet with a glass of water.

- Adults and children over 12 years Two tablets three times each day.
- Skin infections: the usual dose is one tablet twice each day.
- In severe infections, your doctor may increase the dose.

- When to take it

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

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

Take Fucidin[®] tablets with meals to avoid dyspepsia, nausea and vomiting.

- How long to take it

Continue taking Fucidin® tablet for as long as your doctor recommends.

- If you forget to take it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you take more than you should (overdose)

Tell your doctor straight away. You may need to stop taking this medicine.

- If you stop taking it

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.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Fucidin® Tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Fucidin® tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Important information about some of the ingredients of Fucidin® tablet

Fucidin® tablet contain:

-Lactose. This is a type of sugar. If you cannot tolerate any sugar (sometimes called sugar intolerance), contact your doctor before taking this medicine.

- Sodium. Each tablet contains 11 milligrams (mg) sodium. 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.

Driving and using machines

Usually your medicine will have very little 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.

Side effects

Like all medicines, Fucidin® tablet can cause side effects, although not everybody gets them.

Serious side effects:

Allergic reaction: You must get urgent medical help if you have any of the following symptoms:

- difficulty breathing
- Swelling of face or throat swell
- skin develops a severe rash.

You must get urgent medical help if you have any of the following symptoms. You may be developing a

condition called rhabdomyolysis where you develop:

- muscle weakness
- muscle pain
- muscle tenderness
- elevated serum creatine kinase
- acute kidney failure
- dark urine

Number of people affected not known: the level of some cells in your blood may change. You should tell your doctor straight away if you have any of the following symptoms:

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

Number of people affected not known: problems with your liver or kidneys. You should tell your doctor straight away if you have any of the following symptoms:

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

Other possible side effects:

- Nausea, vomiting and dyspepsia

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Fucidin® tablet

- Storage

- Keep out of the reach and sight of

children.

- Do not use Fucidin® Tablets after the expiry date on the carton. The expiry date is the last day of that month.
- Do not store above 30°C.
- Shelf-life: 3 years

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Fucidin® tablets are white to off-white greyish marbled film-coated oval biconvex tablet without embossing.

Fucidin® tablets come in blister packs of 20.

- Ingredients

- Active ingredient
 - Sodium fusidate

Fucidin® tablets contain 250 mg of sodium fusidate in each tablet.

- Inactive ingredients

- Crospovidone
- Hypromellose
- Lactose monohydrate
- Magnesium stearate
- Microcrystalline cellulose
- Silica
- Talc
- Titanium dioxide (E171)
- All-rac- α -tocopherol

You can find important information about some of the ingredients in your medicine near the end of section: Before you use Fucidin® tablet of this leaflet.

- MAL number:

MAL19910821AZ

Manufacturer

Laboratoires LEO
39, route de Chartres
28500 Vernouillet, France

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm
No.1, Jalan SS 7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor,
Malaysia.

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