

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Fucidin® Leo, Tablets, 250 mg

Active ingredient: Each tablet contains sodium fusidate 250 mg.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

Fucidin Leo tablets are used to treat infections caused by staphylococcus bacteria.

Therapeutic group: antibiotics.

2. Before using the medicine

Do not use the medicine if:

- you are hypersensitive (allergic) to the active ingredient (sodium fusidate) or any of the other ingredients this medicine contains (see section 6).

Special warnings regarding the use of the medicine

• **Before the treatment with Fucidin Leo, tell the doctor if:**

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

• While you are taking Fucidin Leo you may be referred by the doctor to 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 the doctor. As with any antibiotic treatment, long-term or repeated use may increase the risk of developing antibiotic resistance.

• 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 Leo tablets.

○ SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the lesions on the torso. In addition, ulcers in the mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin reactions 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, afterwards as an extended rash with a high fever, high liver enzyme levels 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 the beginning of treatment. If you develop a serious rash or another of these skin symptoms, stop using the medicine and refer immediately to the doctor or to receive medical assistance.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional

supplements, tell the doctor or pharmacist.

There may be a drug interaction when taking Fucidin Leo tablets and other medicines, and as a result there may be a need to change the dosage of these medicines.

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

Especially tell the doctor or pharmacist if you are taking:

• Medicines to lower blood cholesterol, such as statins. Taking Fucidin Leo and statins concurrently may lead to muscle weakness, tenderness or pain. See also section 4 "Side effects".

• Oral anti-coagulants (medicines to "thin" blood). You may bleed more easily. Your doctor may change the dosage of the medicine.

• Medicines used to treat HIV (e.g. ritonavir or saquinavir).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before starting treatment with this medicine.

• Do not take Fucidin Leo tablets during pregnancy unless instructed to do so by the doctor.

• If you are breastfeeding or are planning to breastfeed, consult the doctor or pharmacist before starting treatment with 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 to use machines. Consult your doctor if you feel any side effects that may stop you from driving or using machines.

Important information about some of the ingredients of this medicine

• This medicine contains lactose. If you have been told in the past by a doctor that you have an intolerance to some sugars, consult the doctor before starting treatment with this medicine.

• Each tablet contains 11 mg of sodium. You should take this into consideration if you are on a low sodium diet.

Please consult your doctor if you are worried about any ingredient in this medicine.

3. How to use this medicine

Always use this medicine according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is:

Adults:

2 tablets, 3 times a day.

Children:

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

In the case of severe infections, your doctor may increase the dosage.

You should take the medicine at equally spaced times.

Do not exceed the recommended dose.

Manner of administration: The medicine is intended for oral administration. Take the medicine with a glass of water.

Do not halve/crush/chew the tablet. The tablet is coated to mask the taste.

If you have accidentally taken a higher dosage you may experience a sudden onset of vomiting, diarrhea, stomach pain, heartburn, and nausea.

If you have taken an overdose, refer immediately to the doctor. You may need to stop taking the medicine.

If a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take a dose as soon as you remember. Then continue taking this medicine at the regular time. Do not take a double dose to make up for a forgotten dose.

If you stop taking the medicine

It is very important to continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor because the infection may come back.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of Fucidin Leo may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects to look out for:

Refer to the doctor immediately with the appearance of one or more of the following effects. You may need to stop your treatment:

Breathing difficulties, swelling of the face or throat, severe skin rash.

Refer to the doctor immediately with the appearance of one or more of the following effects. You may be suffering from a condition called rhabdomyolysis: Weakness, pain and/or tenderness in the muscles.

Problems with your liver or kidneys. Refer to the doctor immediately with the appearance of one or more of the following effects:

Yellowing of the skin or the whites of your eyes, you are not passing water.

The level of some cells in your blood may change. Refer to the doctor immediately with the appearance of one or more of the following effects:

Unexplained bruising or bleeding, ulcers in the mouth, sore throat or other persistent or recurring infections.

A few cases have been reported of severe skin reactions after taking the medicine, which may develop into potentially life-threatening skin reactions if they are not treated. Refer to the doctor immediately if you experience one or more of the following symptoms. The frequency of these side effects is unknown (effects for which a frequency has not yet been determined):

• Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like spots or circular patches often with central blisters on the lesion on the torso, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. A fever and flu-like symptoms may precede these reactions. Stop using the medicine and refer immediately to the doctor or to receive medical assistance with the appearance of these symptoms. See also section 2.

• Widespread skin rash, high body temperature, elevated liver enzyme levels, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement [Drug Reaction with Eosinophilia and Systemic Symptoms syndrome (DRESS)]. Stop using the medicine and refer immediately to the doctor or to receive medical assistance with the appearance of these symptoms. See also section 2.

• A red, scaly widespread skin rash with pustules and blisters accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis). Stop

using the medicine and refer immediately to the doctor or to receive medical assistance with the appearance of these symptoms.

The following less serious side effects have also been reported. If one or more of these side effects persists for a long time or causes problems, refer to the doctor as soon as possible:

Common side effects (effects that appear in 1-10 out of 100 users):

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

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):

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

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine

• Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.

• **Storage conditions:** No special storage conditions are required. Storage at room temperature is recommended.

• Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Microcrystalline cellulose, lactose monohydrate, crospovidone, talc, hypromellose, magnesium stearate, silica colloidal anhydrous, all-rac- α -tocopherol, titanium dioxide (E171).

What the medicine looks like and what the package contains:

Film coated oval tablet, white to off-white greyish marble-like color, biconvex, without embossing.

Approved package sizes: 12, 36, 100 tablets. Not all package sizes may be marketed.

Manufacturer name and address: Leo Pharmaceutical Products Ltd A/S, Ballerup, Denmark

Revised in March 2020.

Drug registration number at the national drug registry of the Ministry of Health: 100-49-24510-00

Fucidin Leo Tablets 250 mg PIL PB0620-12

Registration holder: **Dexcel® Ltd.**

1 Dexcel St., Or Akiva 3060000, Israel