ANNEX IIIB
Leaflet: Information for the user

FUCIDIN 250 mg, film-coated tablet

Sodium fusidate

Read all this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, or any doubts, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you. Do not pass it on to others, even if they have the same symptoms as you, as it may harm them.
- If any of your side effects get serious or if you notice any side effects not listed in this leaflet, please tell to your doctor or pharmacist. This also applies to any side effects not mentioned in this leaflet. See section 4.

In this leaflet

1. What FUCIDIN 250 mg, film-coated tablet is and what it is used for

This medicine is an antibiotic belonging to the fusidamine family.

The therapeutic indications are based on the antibacterial activity and pharmacokinetic characteristics of sodium fusidate. They take into account both clinical studies performed on this medicine and its place in the range of currently available antibacterial products.

This medicine is indicated for staphylococcal infections only, particularly when located in the skin, bones and joints.

2. What you need to know before you take FUCIDIN 250 mg, film-coated tablet

Do not take FUCIDIN 250 mg, film-coated tablet in the following situations:
- If you are allergic (hypersensitive) to sodium fusidate or any of the other ingredients of this medicine listed in section 6.
- If you are undergoing treatment at the same time with a medicine that reduces blood cholesterol levels (cholesterol-lowering agents) belonging to the statin family (also known as HMG-CoA reductase inhibitors), particularly atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin, due to an increased risk of side effects with these medicines (see also section "Special warnings and precautions for use").

Special warnings and precautions for use
Talk to your doctor or pharmacist before taking this medicine.

This medicine must not be used at the same time as blood cholesterol-lowering medicines belonging to the statin family (also known as HMG-CoA reductase inhibitors), due to the increased risk of muscular side

effects. In rare cases, these muscle problems can be serious, and can cause potentially fatal kidney damage (see section "Do not take FUCIDIN").

Therefore, if you are being treated with a medicine belonging to the statin family, your doctor will decide whether it is best to stop the statin treatment temporarily before starting treatment with FUCIDIN. In this case, treatment by statins could be taken 7 days after the end of treatment by FUCIDIN.

Tell your doctor immediately if you experience muscle pain, painful muscle sensitivity or muscle weakness.

If you have a severe rash associated with other systemic effects (such as fever or fatigue) or if you develop blisters on the skin, sores in the mouth, or inflamed eyes, contact your doctor immediately as these effects can be life threatening.

The use of this medicine may require medical monitoring, particularly in infants and patients with liver disease. If jaundice appears, tell a doctor immediately.

If you are being treated for HIV or human immunodeficiency virus, you must tell your doctor before starting treatment with FUCIDIN (see section Other medicines and FUCIDINE 250 mg film-coated tablet).

This medicine contains 0,48 mmol (11mg) sodium per tablet, equivalent to 0,5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. This should be taken into consideration by patients on a controlled sodium diet.

If your doctor has told you that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Other medicines and FUCIDIN
Due to the increased risk of muscle problems, this medicine must not be taken at the same time as cholesterol-lowering medicines belonging to the statin family (also known as HMG-CoA reductase inhibitors), particularly atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin (see sections "Do not take FUCIDIN" and "Special warnings and precautions for use").

TELL YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING, HAVE RECENTLY TAKEN OR MIGHT TAKE ANY OTHER MEDICINES.

Pregnancy and breast-feeding
Due to the high level of therapeutic benefit, the use of this medicine can be considered at any point during pregnancy, if needed.

If you find out that you are pregnant during the treatment, consult your doctor, as only he or she can decide whether you should continue with the treatment.

Small amounts of this product pass into breast milk.

Ask your doctor or pharmacist for advice before taking any medicines.

FUCIDIN contains lactose and sodium.

3. How to take FUCIDIN 250 mg, film-coated tablet

Due to the kinetics of fusidic acid, it is best to take a loading dose at the start of treatment and then decrease the dose.

Adults:
1 g to 1.5 g/day, which can be increased up to 2 g or 3 g for severe staphylococcal infections.

Children over 6 years:
50 mg/kg/day, which can be increased up to 80 mg/kg/day for severe staphylococcal infections.

For severe staphylococcal infections, the dose can be increased up to 2 to 3 g/day in adults and 80

mg/kg/day in children.

If you have taken more FUCIDIN 250 mg, film-coated tablet than you should:
You may experience gastrointestinal problems.

Consult your doctor or pharmacist immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

4. Possible side effects

Like all medicines, FUCIDIN 250 mg, film-coated tablet can cause side effects, although not everybody gets them.

Common side effects which may affect more than 1 in 10 people:

• vomiting,

• diarrhea,

• abdominal pain,

• difficult digestion (dyspepsia),

• jaundice, increased bilirubin (yellow pigment) in the blood,

• lethargy, fatigue, loss of strength and energy (asthenia).

Uncommon side effects, may affect up to 1 in 100 people:

• decrease in the quantity of certain blood components (pancytopenia, neutropenia, agranulocytosis, thrombocytopenia, anemia including sideroblastic anemia),
• headache,
• drowsiness,
• skin rashes of various types, in particular maculopapular or erythematous, urticaria,
• renal failure.

Rare side effects, may affect up to 1 in 1,000 people:

• hypersensitivity,
• swelling of the neck and face (angioedema).
• pruritus
• erythema

Side effects with not known (frequency cannot be estimated from the available data):

• allergic reaction, exceptionally severe,
• hepatitis or abnormal liver tests,
• redness spreading throughout the body with pustules and accompanied by fever (acute generalized exanthemous pustulosis),
• haemorrhagic lesion of the skin (vascular purpura),
• appearance of bubbles, blisters or peeling of the skin, especially around the mouth, nose, eyes and in the genital area (Stevens-Johnson and Lyell syndromes),
• serious allergic reaction (drug hypersensitivity syndrome / DRESS syndrome) possibly associating several symptoms such as fever, a rash on the skin, an increase in the size of the lymph nodes, severe fatigue, damage to an internal organ, and abnormal blood tests such as an increase in the number of certain white blood cells (eosinophils)
• potentially severe muscle weakness and pain (rhabdomyolysis).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist or nurse. This also applies to any side effects not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and the network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FUCIDIN 250 mg, film-coated tablet

Keep this medicine out of the sight and reach of children.

Do not use FUCIDIN 250 mg, film-coated tablet after the expiry date which is stated on the box.

No special precautions for storage.

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.

6. Contents of the package and other information.

What FUCIDIN 250 mg, film-coated tablet contains

- The active substance is:
  sodium fusidate 250 mg for one 502.4-mg film-coated tablet.
- The other ingredients are: microcrystalline cellulose, crospovidone(1), lactose monohydrate, magnesium stearate, anhydrous colloidal silica, talc, alpha-tocopherol, hypromellose, titanium dioxide.

(1)Crospovidone is a synthetic, cross-linked homopolymer of N-vinyl-2 pyrrolidone.

What FUCIDIN 250 mg, film-coated tablet looks like and the contents of the pack

This medicine is a film-coated tablet. Box of 10 or 100 tablets.

Marketing Authorisation Holder

LABORATOIRES LEO
2 RUE RENE CAUDRON
78960 VOISINS LE BRETONNEUX
FRANCE

Distributor

LABORATOIRES LEO SA
PARC D'AFFAIRES LE VAL SAINT-QUENTIN
2 RUE RENE CAUDRON

78960 VOISINS LE BRETONNEUX
FRANCE

Manufacturer

LEO PHARMA A/S
55 INDUSTRIPARKEN
2750 BALLERUP
DANEMARK

or

LABORATOIRES LEO 39
ROUTE DE CHARTRES
28500 VERNOUILLET
FRANCE

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ADVICE/HEALTH EDUCATION

WHAT DO I NEED TO KNOW ABOUT ANTIBIOTICS?

Antibiotics are effective at fighting infections caused by bacteria. They are not effective against infections caused by viruses.

Your doctor has decided to prescribe you this antibiotic because it is specifically suited to you and your current illness.

Bacteria can survive or reproduce regardless of the effect of an antibiotic. This phenomenon is known as resistance: it makes certain antibiotic treatments ineffective.

Resistance increases when antibiotics are abused or used inappropriately.

You may increase the likelihood of resistant bacteria developing and therefore delay the healing process or even make this medicine ineffective if you do not adhere to:

- The prescribed dose
- The administration times
- The treatment duration.

Consequently, to ensure this medicine remains effective:

1. Only use antibiotics when prescribed to you by your doctor.

2. Follow the instructions on your prescription closely.

3. Do not reuse antibiotics without medical advice, even if you are aiming to treat an illness that appears to be the same.

4. Never give your antibiotics to another person, as they may not be suitable for that person's illness.

5. Once your treatment has finished, return all opened boxes to your pharmacist so this medicine can be disposed of appropriately.