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# ARTWORK

LEO Pharma A/S
SKU & Artwork Management (SAM)

**Status:** **Mock-up for reg. purpose**

| Scale | Get-up | Material No | Sent by e-mail |
|---|---|---|---|
| 100% | PH | 073220-XX | ▼ |
| Subject | | Date | Date |
| INS 140 x 210 mm | | 16/06/2023 | |
| Colour | | Sign. | Sign. |
| Black | | OMADK | |

| Preparation / Strength / Packsize | Place of production |
|---|---|
| Fucidin® suspension - 90 ml | Denmark |
| Comments: | |

| 2. PROOF FROM OMADK | Mock-up Approval Stamp (MAS) | | |
|---|---|---|---|
| Date 10/01/2024 | **Graphic Design** | **Editorial Proof** | **Second Approver** |
| **New proof requested** ☐ | **According to:** SOP_000647, SOP_000962, SOP_003993 and SOP_008676 ☐ | **According to:** SOP_000647, SOP_000962 and SOP_008676 ☐ | Product name ☐ |
| Sign.: | | | Dosage form ☐ |
| | | | Strength/Stripes ☐ |
| Date: | 1st Sign.: Date: | Sign.: Date: | Pack size ☐ |
| | | | Prompts ☐ |
| | 2nd Sign.: Date: | | Material No./Reg. No. ☐ |
| | | | Barcode ☐ |
| | | | Sign.: Date: |

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# Fusidic Acid

## Fucidin® 50 mg/mL Suspension Antibacterial (Steroid)

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**Formulation**
Each ml suspension contains:
Fusidic acid (as Hemihydrate), Ph. Eur.....50mg in banana-flavoured, aqueous suspension.
Other constituents: Acesulfame potassium, Banana flavour, Citric acid monohydrate, Disodium phosphate dihydrate, Hydroxyethylcellulose, Glucose liquid, Methylcellulose, Orange dry flavour, Sodium benzoate, Sorbitol, Purified water.

**Product Description**
Cream coloured suspension with odour of banana.

**Indications**
Fucidin® suspension is indicated for the treatment of infections caused by susceptible organisms, especially staphylococci, e.g. osteomyelitis, septicaemia, endocarditis, superinfected cystic fibrosis, pneumonia, skin and soft tissue infections, surgical and traumatic wound infections.

**Dosage and Route of Administration**
Oral Suspension
Children and infants:
1 ml of suspension (50 mg) per kg body weight daily divided into 3 equal doses
1–5 years: 5 ml 3 times daily
5–12 years: 10 ml 3 times daily
Adult dose: 15 ml 3 times daily

**Precautions**
Statins (HMG-CoA reductase inhibitors) and systemic Fucidin® must not be co-administered, (see Contraindications). There have been reports of rhabdomyolysis (including fatalities) in patients receiving this combination. Statin treatment should be discontinued throughout the duration of treatment with systemic Fucidin®. The patient should be advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain or tenderness. Statin therapy may be re-introduced seven days after the last dose of systemic Fucidin®. In exceptional circumstances, where prolonged systemic Fucidin® is needed, e.g. for the treatment of severe infections, the need for co-administration of HMG-CoA reductase inhibitors and systemic Fucidin® should only be considered on a case by case basis and under close medical supervision.
Fusidic acid is metabolised in the liver and excreted in the bile. Elevated liver enzymes and jaundice have occurred during systemic Fucidin® therapy but are usually reversible on discontinuation of the drug.
Systemic Fucidin® should be given with caution and liver function should be monitored if used in patients with hepatic dysfunction. Caution is required in patients with biliary disease and biliary tract obstruction. Caution is required in patients treated with HIV-protease inhibitors (See Drug Interaction). Fusidic acid competitively inhibits binding of bilirubin to albumin. Caution is necessary if systemic Fucidin® is administered to patients with impaired transport and metabolism of bilirubin. Particular care is advised in neonates due to the theoretical risk of kernicterus.
Bacterial resistance has been reported to occur with the use of fusidic acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.
For Fucidin® oral suspension only:
Patients with rare hereditary problems of fructose intolerance should not take this medicine due to its content of sorbitol (E420).
For Fucidin® oral suspension only:
Patients with rare glucose-galactose malabsorption should not take this medicine due to its content of glucose.

**Contraindications:**
Hypersensitivity to the active substance or to any of the excipients.
Concomitant treatment with statins (HMG-CoA reductase inhibitors). See Drug Interaction, Precautions.

**Fertility, pregnancy and lactation**
Pregnancy:
There are no or limited data (less than 300 pregnancy outcomes) from the use of fusidic acid in pregnant women. Animal studies do not indicate direct or indirect harmful effect with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of systemic Fucidin® during pregnancy.
Breast-feeding:
Physico-chemical data suggest excretion of fusidic acid in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from systemic Fucidin® therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.
Fertility:
There are no clinical studies with systemic Fucidin® regarding fertility. Pre-clinical studies did not show any effect of sodium fusidate on the fertility in rats.

**Adverse Drug Reaction**
The estimation of the frequency of undesirable effects is based on a pooled analysis of data from clinical trials and from spontaneous reporting.
The most frequently reported undesirable effects of Fucidin® administered orally are gastrointestinal disorders like abdominal discomfort and pain, diarrhoea, dyspepsia, nausea and vomiting. Anaphylactic shock has been reported.
Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported. Within each frequency group, adverse reactions are presented in the order of decreasing seriousness.

Very common (≥1/10)
Common (≥1/100 to < 1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)

**CCSI text:**

| | |
|---|---|
| **Blood and lymphatic system disorders** | |
| Uncommon | Pancytopenia<br>Leukopenia[a]<br>Thrombocytopenia<br>Anaemia |
| **Immune system disorders** | |
| Uncommon | Anaphylactic shock/anaphylactic reaction |
| Rare | Hypersensitivity |
| **Nervous system disorders** | |
| Uncommon | Headache<br>Somnolence |
| **Gastrointestinal disorders** | |
| Common | Vomiting<br>Diarrhoea<br>Abdominal pain<br>Dyspepsia<br>Nausea<br>Abdominal discomfort |
| **Hepatobiliary disorders** | |
| Uncommon | Hepatic failure<br>Cholestasis<br>Hepatitis[b]<br>Jaundice[c]<br>Hyperbilirubinaemia<br>Liver function test abnormal[d] |
| Rare | Hepatic function abnormal |
| **Skin and subcutaneous tissue disorders** | |
| Uncommon | Acute generalized exanthematous pustulosis<br>Urticaria<br>Pruritus<br>Rash[e]<br>Erythema |
| Rare | Angioedema |
| **Musculoskeletal and connective tissue disorders** | |
| Uncommon | Rhabdomyolysis[f] |
| **Renal and urinary disorders** | |
| Uncommon | Renal failure[g] |
| **General disorders and administration site conditions** | |
| Common | Lethargy/Fatigue/Asthenia |

a) Haematological disorders affecting the white cell line (neutropenia, granulocytopenia and agranulocytosis) have been reported.
b) Hepatitis also includes Hepatitis cholestatic /Cytolytic hepatitis
c) Jaundice also includes Jaundice cholestatic
d) Including alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased, blood bilirubin increased and gammaglutamyltransferase increased
e) Rash includes various types of rash reactions such as drug eruption, erythematous and maculo-papular rash
f) Rhabdomyolysis may be fatal
g) Renal failure also indcludes renal failure acute

Paediatric population
Frequency, type and severity of adverse reactions in children are expected to be the same as in adults, based on limited data.

**Overdosage**
Acute symptoms of overdose include gastrointestinal disturbances. Management should be directed towards alleviation of symptoms. Dialysis will not increase the clearance of fusidic acid. An overdose of 4 g/day for a duration of ten days in an adult has been reported without any adverse events. An overdose of 1,250 mg/day for a duration of seven days in a child (three years old) has been reported without any adverse events.

**Pharmacological Properties**
**Pharmacodynamic properties**
**Pharmacotherapeutic group:**
Steroid antibacterials,. ATC code: J01XC01
Fucidin® exerts powerful activity against a number of gram-positive organisms.
Staphylococci, including the strains resistant to penicillin and other antibiotics, are particularly susceptible to Fucidin®. Concentrations of 0.03-0.12 mcg/ml inhibit nearly all strains of *Staphylococcus aureus.*
**Pharmacokinetic properties**
Fucidin® readily penetrates the central nervous system when the meninges are inflamed and is widely distributed in the body.
Bactericidal levels have been assayed in bone and necrotic tissue. Blood levels are cumulative, reaching concentrations of 50-100 mcg/ml after oral administration of 1.5 g daily for 3 to 4 days.
Fucidin® is excreted mainly in the bile, little or none being excreted in the urine.
Preclinical Safety data There are no preclinical data of relevance to the prescriber which are additional to that already Included in other areas of the SPC.

**Incompatibilities:**
Not applicable

**Drug interaction:**
Statins (HMG-CoA reductase inhibitors)
Concomitant treatment with statins (HMG-CoA reductase inhibitors) is contraindicated.
Co-administration of systemic Fucidin® and statins may cause possibly fatal rhabdomyolysis.
Treatment with statins should therefore be discontinued throughout the duration of the treatment with systemic Fucidin®. Statin therapy may be reintroduced seven days after the last dose of systemic Fucidin®. (See section Precautions, Contraindications).

Oral anticoagulants
Systemic Fucidin® administered concomitantly with oral anticoagulants such as coumarin derivatives or anticoagulants with similar actions may alter the anticoagulant effect.
Adjustment of the oral anticoagulant dose may be necessary in order to maintain the desired level of anticoagulation.
HIV protease inhibitors Co-administration of systemic Fucidin® and HIV protease inhibitors such as ritonavir and saquinavir may cause increased plasma concentrations of both agents which may result in hepatotoxicity. Concomitant use is not recommended. (See Precautions)

**Storage condition/Shelf life:**
Store at temperatures not exceeding 30°C. Shelf life: 36 months.

**Instructions and Special Precautions for Handling and Disposal:**
Shake well before use. No special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

**Dosage Form and Packaging Available:**
Oral Suspension
90 mL net content in 100 mL Amber Glass Bottle with 20 mL Polypropylene cap and 5 mL Polystyrene spoon
(Box of 1's bottle)

Shake well before use

Caution: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

**ADR Reporting Statement:**
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph and to the DKSH Market Expansion Services Philippines, Inc. Pharmacovigilance at pharmacovigilance.ph@dksh.com or hotline +63998-965-4158.
The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

**Registration Number:**
DR-XY7269

Manufactured by:
LEO Pharma A/S
Industriparken 55, Ballerup 2750, Denmark

Imported and Distributed by:
DKSH Market Expansion Services Philippines, Inc.
3rd Floor Science Hub Tower 2 Campus Avenue, McKinley Hill Cyberpark, Pinagsama, Taguig City, Metro Manila

Date of First Authorization
05 March 2003

**The leaflet was last revised in December 2023**

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