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	073213-XX	▼
Subject: INS 175 x 280 mm		Date: 11/01/2024	Date
Colour: Black		Sign.: OMADK	Sign.

Preparation Strength Packsize	Place of production
Fucidin® ointment	Ireland

Comments:
Page 1 of 2 Font size: 9 pt Pharmacode: 439

439

IIE007-01 - 175 x 280 mm

175 mm

280 mm

SODIUM FUSIDATE

Fucidin®

20mg/g Ointment

Antibacterial

PRODUCT DESCRIPTION
Ointment
Off-white viscous ointment

Formulation:
Each g of ointment contains:
Sodium Fusidate, Ph. Eur.....20 mg

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Fucidin® ointment 2% contains Sodium Fusidate, a potent topical antibacterial. Fusidic acid and its salts exhibit fat and water solubility properties with strong surface activity, and show unusual ability to penetrate intact skin. However, they are poorly systemically absorbed after topical administration.

Concentrations of 0.03 - 0.12 mcg/ml inhibit nearly all strains of Staphylococcus aureus. Topical Fucidin® is also active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

Pharmacokinetic Properties

There are no data which define the pharmacokinetics of Fucidin® Ointment, following topical administration in man.

However, in-vitro studies show that fusidic acid and its salts can penetrate intact human skin in concentrations well above the MIC value of susceptible organisms.
The degree of penetration depends on factors such as the duration of exposure to fusidic acid (or its salts) and the condition of the skin. Fusidic acid and its salts are excreted mainly in the bile with little excreted in the urine.

INDICATIONS
Fusidate sodium (Fucidin®) ointment is indicated for treatment of skin infections caused by staphylococci, streptococci, Corynebacterium minutissimum and other organisms sensitive to sodium fusidate; the most important indications being:

Impetigo	Boils	Hidradenitis
Infected wounds	Sycosis barbae	Paronychia
Folliculitis	Carbuncles	Erythrasma

DOSAGE AND ROUTE OF ADMINISTRATION
Fusidate sodium (Fucidin®) ointment is applied to the affected area 2–3 times daily, generally for a period of 7 days. It can be used with or without a covering dressing.
Caution should be observed when applying Fusidate sodium (Fucidin®) ointment in the eye region as this preparation may cause irritation if it gets into the eye.

CONTRAINDICATIONS
Hypersensitivity to the active substance or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Bacterial resistance among Staphylococcus aureus has been reported to occur with the use of topical Fucidin®. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance.

Fucidin® ointment contains cetyl alcohol and hydrous lanolin. These excipients may cause local skin reactions (e.g. contact dermatitis). Fucidin® ointment contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

When Fucidin® ointment is used on the face; care should be taken to avoid the eyes as the excipients in the ointment may cause conjunctival irritation.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
No interaction studies have been performed. Interactions with systemically administered medicinal products are considered minimal as the systemic absorption of topical Fucidin® is negligible.

FERTILITY, PREGNANCY AND LACTATION
Fertility
There are no clinical studies with topical Fucidin® regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically applied fusidic acid/sodium fusidate is negligible.

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to topically applied fusidic acid/sodium fusidate is negligible. Topical Fucidin® can be used during pregnancy.

Breast-feeding
No effects on the breastfed new-born/infant are anticipated since the systemic exposure of topically applied fusidic acid/sodium fusidate to the breast-feeding woman is negligible. Topical Fucidin® can be used during breast-feeding but it is recommended to avoid applying topical Fucidin® on the breast.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES
Fucidin® administered topically has no or negligible influence on the ability to drive or to use machines.

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Mock-up Approval Stamp (MAS)

2. PROOF FROM DVRDK
Date 12/01/2024

New proof requested ☐
Sign.:
Date:

Graphic Design
According to: SOP_000647, SOP_000962, SOP_003993 and SOP_008676
1st Sign.: Date:
2nd Sign.: Date:

Editorial Proof
According to: SOP_000647, SOP_000962 and SOP_008676
_ ☐
Sign.: Date:

Second Approver

Product name	☐
Dosage form	☐
Strength/Stripes	☐
Pack size	☐
Prompts	☐
Material No./Reg. No.	☐
Barcode	☐

Sign.: Date:

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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.

Based on pooled data from clinical studies including 4724 patients who received Fucidin® cream or Fucidin® ointment, the frequency of undesirable effects is 2.3%.

The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by various application site conditions such as pain and irritation, which all occurred in less than 1% of patients.

Hypersensitivity and angioedema have been reported.

Undesirable effects are listed by MedDRA System Organ Class (SOC) and the individual undesirable effects are listed starting with the most frequently reported. Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness.
Very common ≥1/10
Common ≥1/100 and < 1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥1/10,000 and <1/1,000
Very rare <1/10,000

Immune system disorders	
Rare: (≥1/10,000 and <1/1,000)	Hypersensitivity
Eye disorders	
Rare: (≥1/10,000 and <1/1,000)	Conjunctivitis
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Dermatitis (incl. dermatitis contact, eczema) Rash* Pruritus Erythema *Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and papular have been reported. Rash generalised has also occurred.
Rare: (≥1/10,000 and <1/1,000)	Angioedema Urticaria Blister
General disorders and administration site conditions	
Uncommon: (≥1/1,000 and <1/100)	Application site pain (incl. skin burning sensation) Application site irritation

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

OVERDOSE
Overdose is unlikely to occur.

STORAGE
Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE
Ointment
Aluminum tube x 5 g and 15 g
(Box of 1's)

Keep out of reach of children.

FOR EXTERNAL USE ONLY.

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.

Manufactured by:
LEO Laboratories Ltd, 285, Cashel Road, Crumlin, Dublin 12, Ireland

For: LEO Pharma A/S, 55 Industriparken, DK-2750, Ballerup, 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

REGISTRATION NUMBER
DR-1170

DATE OF FIRST AUTHORIZATION
July 1975

DATE OF REVISION OF PACKAGE INSERT
November 2023

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