Fucidin®
Plain topical antibiotic

Ointment
Sodium fusidate 20 mg/g in neutral ointment base.

Pack Sizes: 5g, 15g

Product Description
Translucent yellowish to white ointment.

Properties
Sodium fusidate, an antibiotic derived from Fusidium coccineum, exerts powerful antibacterial activity against a number of gram-positive organisms.
Staphylococci, including the strains resistant to penicillin or to other antibiotics, are particularly susceptible to sodium fusidate. The therapeutic efficacy of topically applied Fucidin® ointment is due partly to the pronounced antibacterial activity of sodium fusidate against the organisms responsible for skin infections, and partly to the unique ability of this antibiotic to penetrate intact skin.

Indications
Fucidin® ointment is indicated for the treatment of skin infections caused by staphylococci, streptococci, Coryne-bacterium minutissimum, and other organisms sensitive to sodium fusidate. The most important indications being:

Impetigo	Boils	Carbuncles	Paronychia
Infected wounds	Sycosis barbae	Hidradenitis	Erythrasma
Folliculitis			

Application
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 Fucidin® ointment in the eye region as this preparation may cause irritation if it gets into the eye.

Special Warning and Precautions of 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 wool fat (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) and 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.

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

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.

Undesirable Effects

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.

List of Excipients
wool fat (lanolin)
cetyl alcohol
liquid paraffin
white soft paraffin
all-rac-α-tocopherol
butylhydroxytoluene (E321)

Incompatibilities
Fucidin® ointment is a ready-for-use preparation and should, therefore, not be mixed with other ingredients or preparations.

Storage
Do not store above 30°C.

This leaflet was last revised in November 2017.
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Ballerup – Denmark

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