Fucikalt®

Sodium Fusidate

FORMS AND PRESENTATION.
Fucikalt®: Ointment: Tube of 15 g.

COMPOSITION
Fucikalt®: Each 1 g contains Sodium fusidate 20 mg.
Excipients: Cetyl alcohol, wool fat (lanolin), butylhydroxytoluene, liquid paraffin, white soft paraffin.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: Other antibiotics for topical use.
ATC code: D06AX01
Sodium fusidate is a potent topical antibacterial agent. Sodium Fusidate shows fat and water solubility and strong surface activity and exhibits an unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 microgram/ml inhibit nearly all strains of *Staphylococcus aureus*. The topical application of sodium fusidate is also effective against streptococci, corynebacteria, Neisseria, and certain clostridia.

Pharmacokinetic properties
In vitro studies show that sodium fusidate can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to sodium fusidate and the condition of the skin. Sodium fusidate is excreted mainly in the bile with little excreted in the urine.

INDICATIONS
Fucikalt® is indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of *Staphylococcus aureus, streptococcus spp,* and *Corynebacterium minutissimum*. Primary skin infections that may be expected to respond to treatment with sodium fusidate applied topically include impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia, and erythrasma; also, such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis, and infected cuts /abrasions.

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

PRECAUTIONS
Bacterial resistance among *staphylococcus aureus* has been reported to occur with the use of topical Fucikalt®. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

Extended or recurrent use may increase the risk of developing contact sensitization.
Fucikalt® ointment contains cetyl alcohol and lanolin. These excipients may cause local skin reactions (e.g. contact dermatitis).

Fucikalt® ointment contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

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

Instruct patients not to smoke or go near naked flames – risk of severe burns.
Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Effects on ability to drive and use machines
Fucikalt® administered topically has no or negligible influence on the ability to drive or to use machines.

PREGNANCY AND LACTATION
Pregnancy
No effects during pregnancy are anticipated since systemic exposure to topically applied sodium fusidate is negligible. Topical Fucikalt® can be used during pregnancy.

Breast-feeding
No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of topically applied Fucikalt® to the breastfeeding woman is negligible. Topical Fucikalt® can be used during breastfeeding, but it is recommended to avoid applying it on the breast.

DRUG INTERACTIONS
No interaction studies have been performed. Interactions with systemically administered medicinal products are

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considered minimal as the systemic absorption of topical sodium fusidate is negligible.

ADVERSE 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 patients who received Fucikalt® cream or Fucikalt® 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 also.

Undesirable effects are listed below. Frequency categories are defined according to the following convention: 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: Hypersensitivity (rare)
Eye disorders: Conjunctivitis (rare)
Skin and subcutaneous tissue disorders: Dermatitis (including dermatitis contact, eczema), rash (various types of rash reactions such as erythematous, pustular, vesicular, maculopapular, and papular rash have been reported. Generalized rash has also occurred), pruritus, erythema (uncommon); Angioedema, urticaria, blister (rare)
General disorders and administration site conditions: Application site pain (including skin burning sensation), application site irritation (uncommon)

Pediatric population
The frequency, type, and severity of adverse reactions in children are expected to be the same as in adults.

DOSAGE AND ADMINISTRATION
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Adults and Pediatric Population
Uncovered lesions - apply gently, three or four times daily.
Covered lesions - less frequent applications may be adequate.

Method of administration
Cutaneous use.

OVERDOSAGE
Overdose is unlikely to occur.
Unless hypersensitivity to sodium fusidate or any of the excipients exists, accidental ingestion of Fucikalt® ointment is unlikely to cause any harm. The total quantity of sodium fusidate (15g Fucikalt® ointment contains 300mg sodium fusidate) will usually not exceed the approved total daily oral dose of sodium fusidate containing products except in children aged less than 1 year and weighing ≤ 10 kg. Although in this instance a child of this age group is unlikely to ingest a whole tube of Fucikalt® ointment. The concentration of the excipients is too low to constitute a safety risk.

STORAGE CONDITIONS
Store below 30˚C
Keep in original pack in intact conditions.

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Marketing Authorization Holder
Benta S.A.L. - Lebanon

Manufacturer
Manufactured by Benta Lyon S.A.S. Saint Genis Laval, France
For Benta S.A.L. Lebanon.

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