Fucibet®: A Combination of Fusidic Acid and Betamethasone in One Convenient Lipid Cream Product*

Fusidic acid 2%
(antibiotic)

+

Betamethasone valerate 0.1%
(corticosteroid)

=

Available in 30g tubes

Fucibet®: Dosage and Administration

For up to 2 weeks

For both adults and children over 6 years of age, apply a **thin layer** to the affected area **twice daily** until a satisfactory response is obtained.

A single treatment course should not exceed 2 weeks.

Fucibet®: Demonstrated Low Rate of Resistance to *S. aureus* (<3%)*

Fusidic acid is predominantly active against Gram-positive bacteria, and highly effective against *S. aureus*, including methicillin-resistant strains.

In a sensitivity study of **2,302** *S. aureus* strains isolated over a 6-year period:

- **Only 2.8%** were found to be resistant to fusidic acid
- Bi-annual resistance rates ranged **from 0.7 to 6.3%**
- **Just 4.2% of the 240 MRSA strains** detected were resistant to fusidic acid

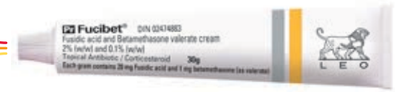
* Clinical significance has not been established.
MRSA, methicillin-resistant *Staphylococcus aureus*.

Fucibet®: Fusidic Acid and Betamethasone Valerate Combined in a Lipid Cream Product*

Fusidic Acid 2%
antibiotic

Betamethasone Valerate 0.1%
corticosteroid

Lipid Cream
vehicle



Summary*

Compared to lipid cream vehicle and after two weeks of treatment,

- **Fucibet®** demonstrated a greater:
  - Reduction in Total Severity Score
  - Patient response rate
  - Bacteriological response
- **Fucibet®** demonstrated a low total rate of adverse events

Clinical use:
Fucibet® is suitable in cases where treatment with a potent corticosteroid is appropriate to manage the pruritus and inflammation associated with eczematous dermatoses, and is intended for use during flare-ups for short-term (up to 2 weeks) treatment against bacteria susceptible to fusidic acid.

To reduce the development of drug-resistant bacteria, Fucibet® should only be used to treat infections that are proven or strongly suspected to be caused by bacteria.

Safety and efficacy has been established in patients ≥6 years old. Use with caution in pediatric patients.

Contraindications:
- Systemic fungal infections
- Primary skin infections caused by fungi, virus or bacteria
- Skin eruptions associated with tuberculosis or syphilis
- Perioral dermatitis and rosacea
- Eruptions following vaccinations

Relevant warnings and precautions:
- Avoid long-term continuous use
- Risk of systemic absorption
- Should not be used under occlusive dressing, over extensive areas, or on the face, scalp, axillae or scrotum
- Risk of HPA-axis suppression; Cushing's syndrome, hyperglycemia, and glycosuria
- Susceptibility to infections
- Use with care near eyes
- Risk of bacterial resistance or microbial overgrowth
- Skin atrophy
- Safety during pregnancy or lactation has not been established

For more information:
Please consult the Product Monograph at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The Product Monograph is also available by calling LEO Pharma Medical Information at 1-800-263-4218.

* See reverse page for full study design.

Reference:
1. Fucibet® Product Monograph. LEO Pharma Inc. April 12, 2018.

Available now

Fucibet®
Fusidic acid / betamethasone valerate

The **Power of Fucibet®**: Fusidic Acid plus Betamethasone Valerate

Fucibet® (fusidic acid and betamethasone valerate) is indicated for the topical treatment of **eczematous dermatoses** including atopic eczema, discoid eczema, stasis eczema and seborrhoeic eczema when secondary bacterial infection caused by *Staphylococcus aureus* is confirmed or suspected.[1]

Fucibet®
Fusidic acid / betamethasone valerate

Fucibet®
Fusidic acid / betamethasone valerate

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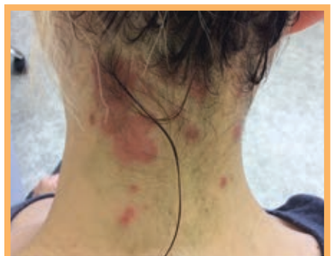
Fucibet®
Fusidic acid / betamethasone valerate

LEO

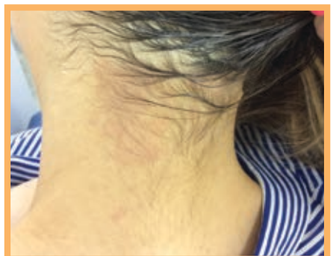
Fucibet®: Demonstrated Efficacy in Eczematous Dermatoses with Secondary Bacterial Infection caused by *S. aureus*

Demonstrated Visible Results at Week 2

Real patient cases treated with Fucibet®:

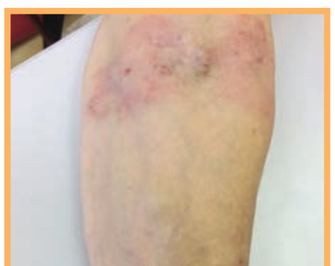


Baseline (Week 0)

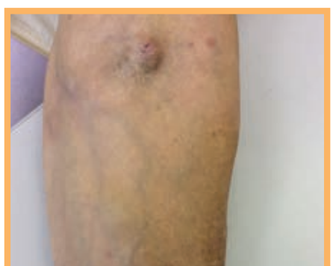


Week 2

Actual patient photos. 37-year-old female patient with infected dermatitis at baseline, treated with Fucibet® twice daily for 2 weeks. Individual results may vary.



Baseline (Week 0)



Week 2

Actual patient photos. 73-year-old female patient with infected dermatitis at baseline, treated with Fucibet® twice daily for 2 weeks. Individual results may vary.

Fucibet® was Significantly Superior in Reducing Total Severity Score (TSS)* vs. Lipid Cream Vehicle

33% **reduction** with lipid cream vehicle

VS

Nearly **83%** **reduction** with Fucibet® treatment

in TSS at treatment end (Week 2) (p<0.001).[1]*

Fucibet® had a Greater Patient Response Rate vs. Lipid Cream Vehicle

3 out of 10 **patients (30%)** treated with lipid cream vehicle

VS

8 out of 10 **patients (83%)** treated with Fucibet®

showed marked improvement or complete clearance with twice-daily treatment (p<0.001).[1]*

Fucibet® had a Significantly Superior Bacteriological Response vs. Lipid Cream Vehicle

25% **of patients** treated with lipid cream vehicle

VS

88% **of patients** treated with Fucibet®

demonstrated a successful bacteriological response with twice-daily treatment (p<0.001).[1]*

Fucibet®: Demonstrated Established Safety Profile

The total rate of adverse events was:

21.6% **lipid cream vehicle**

VS

13.5% **Fucibet®**

- Lesional/peri-lesional adverse events were 13.6% for lipid cream vehicle vs. **2.6% for Fucibet®**.
- The most frequently reported adverse drug reactions were pruritus and skin burning sensation.

* A randomized, double-blind, three-arm, comparative trial of 629 patients with clinically-infected atopic dermatitis. Patients were treated with either twice-daily Fucibet® (n=275), fusidic acid/betamethasone valerate cream (n=264), or lipid cream vehicle (n=90) for two weeks. The primary endpoint for overall clinical response was the percentage reduction/change in total severity scores (TSS) from baseline to end of treatment. TSS was calculated based on the severity of erythema, edema, oozing/crusting and excoriation, each assessed at a 4-point scale. In addition, for overall treatment efficacy patients with marked improvement or complete clearance were defined as responders.

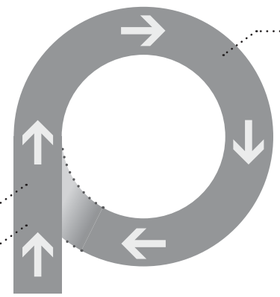
Fucibet®: The Combined Action of Fusidic Acid and Betamethasone Valerate

Dual Inhibition of Inflammation and Bacterial Protein Synthesis[1]*

Betamethasone valerate†
Inhibition of inflammatory mediators; antipruritic and vasoconstrictive actions

Mediators of **inflammation, pruritus and vasoconstriction**

Itching and scratching



Eczematous dermatoses

***S. aureus* colonization**

Fusidic acid‡
Inhibition of bacterial protein synthesis

† The mechanism of anti-inflammatory activity of TCSs is unclear. It is thought to induce lipocortins, which are postulated to control the biosynthesis of potent mediators of inflammation.

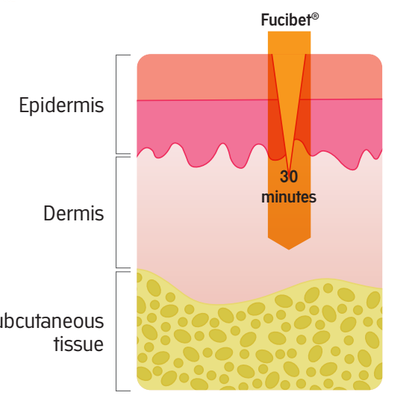
‡ Interferes with amino acid transfer to ribosomes and primarily active against Gram-positive bacteria, in particular *S. aureus* including MRSA, *Streptococcus spp.*, *C. minutissimum*, some *Neisseria spp.*, and certain *Clostridium spp.*; mainly bacteriostatic but may be bactericidal at higher concentrations.

The Penetration of Fusidic Acid[1]*

In vitro studies demonstrated that up to:

- **2.5%** of topically applied fusidic acid could **cross intact human skin within 30 minutes**.
- **Up to 10%** of the applied dose could **penetrate down into the stratum corneum** of the skin, reaching **levels well above the MIC** required for sensitive *S. aureus* strains.*

The degree of penetration depends on factors such as the duration of exposure and the condition of the skin and the site of application.



* Clinical significance has not been established.
MIC, minimal inhibitory concentration; MRSA, methicillin-resistant *Staphylococcus aureus*; TCSs, topical corticosteroids.