

NEW ZEALAND DATA SHEET

1 FUCICORT® Cream

Fucicort® fusidic acid 20 mg/g and betamethasone 1 mg/g (as valerate) cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains active ingredients fusidic acid 20mg and betamethasone (as valerate) 1mg.

Excipients of known effect: cetostearyl alcohol 72 mg/g and chlorocresol 1 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Fucicort® is a white cream containing fusidic acid and betamethasone valerate in a water miscible base.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fucicort® is indicated in inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, seborrheic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

4.2 Dosage and method of administration

Uncovered lesions:

A small quantity should be applied to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

Covered lesions:

In the more resistant lesions the effect of Fucicort® cream can be enhanced by occlusion with polyethylene film. Overnight occlusion is usually adequate.

4.3 Contraindications

- Hypersensitivity to fusidic acid/sodium fusidate, betamethasone valerate or to any of the excipients (see section 6.1).
- Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment (see section 4.4)
- Systemic fungal infection.
- Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy.

- Perioral dermatitis and rosacea.
- Ulcerative conditions.
- The use of fluorinated steroids is contraindicated on the face.

4.4 Special warnings and special precautions for use

Long-term continuous topical therapy with Fucicort® should be avoided.

Although rare, hypersensitivity reactions to fusidic acid have been reported. Should hypersensitivity occur, applications should be stopped immediately.

When steroids and particularly fluorinated steroids are applied for long periods of time (more than four weeks) the occurrence of atrophic striae is likely.

Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fucicort®.

Due to the content of corticosteroid, Fucicort® should be used with care near the eyes. Avoid getting Fucicort® into the eyes (see section 4.8).

Due to the content of betamethasone valerate, prolonged topical use of Fucicort® may cause skin atrophy.

Atopic dermatitis (eczema)

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations.

Use in psoriasis

Topical corticosteroids should be used with caution in psoriasis as rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis, careful patient supervision is important.

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression

Manifestations of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above is observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency. Routine steroid precautions must be observed particularly if the patient is stressed (e.g. following surgery)

Risk factors of increased systemic effects are:

- Potency and formulation of topical steroid
- Duration of exposure
- Application to a large surface area
- Use on occluded areas of skin e.g. on intertriginous areas or under occlusive

dressings with weekly doses of over 30g (note that nappies can be occlusive)

- Increased hydration of the stratum corneum
- Use on thin areas such as the face
- Use on broken skin or other condition where the skin barrier may be impaired
- In comparison with adults, children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic adverse effects. This is because children have an immature skin barrier and a greater surface area to the body weight ratio compared with adults.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroid.

Prolonged use on flexures and intertriginous areas is undesirable.

Bacterial resistance has been reported to occur with the topical use of fusidic acid. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance. Limiting therapy with topical fusidic acid and betamethasone valerate to no more than 14 days at a time will minimise the risk of developing resistance.

This also prevents the risk that the immunosuppressive action of corticosteroid might mask any potential symptoms of infections due to antibiotic-resistant bacteria.

Due to the content of corticosteroid having immunosuppressant effect, Fucicort® may be associated with increased susceptibility to infection, aggravation of existing infection, and activation of latent infection. It is advised to switch to systemic treatment if infection cannot be controlled with topical treatment.

Fucicort® contains cetostearyl alcohol and chlorocresol as excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

4.5 Interactions with other medicinal products and other forms of interactions

No interaction studies have been performed. Interactions with systemically administered medicinal products are considered minimal.

4.6 Fertility, pregnancy and lactation

Pregnancy

Fusidic acid:

No effects during pregnancy are anticipated, since systemic exposure to fusidic acid is negligible.

Betamethasone valerate:

There are no or limited amount of data from the use of topical betamethasone valerate in pregnant women. Studies in animals have shown reproductive toxicity.

Fucicort® should not be used during pregnancy unless the clinical condition of the woman requires treatment with fusidic acid and betamethasone valerate.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of topically applied fusidic acid and betamethasone valerate to a limited area of skin of the breastfeeding woman is negligible.

Fucicort® can be used during breastfeeding but it is recommended to avoid applying Fucicort® on the breast.

Fertility

There are no clinical studies with Fucicort® regarding fertility.

4.7 Effect on ability to drive and use machines

Fucicort® has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The estimation of the frequency of undesirable effects is based on a pooled analysis of data from clinical studies and spontaneous reporting.

The most frequently reported adverse reaction during treatment is pruritus.

Undesirable effects are listed by MedDRA 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 $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ and $< 1/1,000$

Very rare $< 1/10,000$

Immune system disorders	
Uncommon ($\geq 1/1,000$ and $< 1/100$)	Hypersensitivity
Skin and subcutaneous tissue disorders	
Uncommon ($\geq 1/1,000$ and $< 1/100$)	Dermatitis contact Eczema (condition aggravated)

	Skin burning sensation Pruritus Dry skin
Rare ($\geq 1/10,000$ and $< 1/1,000$)	Erythema Urticaria Rash (including rash erythematous and rash generalised)
General disorders and administration site conditions	
Uncommon ($\geq 1/1,000$ and $< 1/100$)	Application site pain Application site irritation
Rare ($\geq 1/10,000$ and $< 1/1,000$)	Application site swelling Application site vesicles

Systemic undesirable class effects of corticosteroids like betamethasone valerate include adrenal suppression especially during prolonged topical administration (see section 4.4). Although very rare, examples of systemic effects affecting the endocrine system include: Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushingoid features (e.g. moon face, central obesity), delayed weight gain/growth retardation in children, osteoporosis, hyperglycaemia/glucosuria, cataract, hypertension, increased weight/obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis.

Raised intra-ocular pressure and glaucoma may also occur after topical use of corticosteroids near the eyes, particularly with prolonged use and in patients predisposed to developing glaucoma (see section 4.4).

Dermatological undesirable class effects of potent corticosteroids include: skin atrophy/skin thinning, allergic contact dermatitis/dermatitis (incl. dermatitis contact and dermatitis acneiform), perioral dermatitis, pustular psoriasis (when used for psoriasis indication), skin striae, skin wrinkling, telangiectasia, rosacea, erythema, hypertrichosis, hyperhidrosis, and depigmentation and exacerbation of underlying inflammatory dermatoses. Ecchymosis may also occur with prolonged use of topical corticosteroids.

Class effects for corticosteroids have been uncommonly reported for Fucicort® as described in the frequency listing above.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

For topically applied fusidic acid, no information concerning potential symptoms and signs due to overdose administration is available. Cushing's syndrome and adrenocortical

insufficiency may develop following topical application of corticosteroids in large amounts and for more than three weeks.

Systemic consequences of an overdose of the active substances after accidental oral intake are unlikely to occur. The amount of fusidic acid in one tube of Fucicort® does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

For advice on the management of overdose please contact the National Poisons Centre 0800 POISON (0800 764 766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D07CC01

Pharmacotherapeutic group: Corticosteroids, potent, combinations with antibiotics, dermatological preparations.

Mechanism of action

Fucicort® cream is a combination preparation containing the corticosteroid betamethasone valerate and the antibiotic, fusidic acid.

Betamethasone belongs to the group of potent corticosteroid (class III) and exerts its effect by suppressing local immunoreactions, including vasodilatation, swelling and soreness.

Fusidic acid inhibits bacterial protein synthesis. Fusidic acid binds to elongation factor G (EF-G), preventing release of the EF-G-guanosine diphosphate complex, which stall the protein synthesis. Fusidic acid has bacteriostatic activity at low concentrations but bactericidal activity at high concentrations.

Susceptibility

Fusidic acid is primarily active against Gram-positive bacteria, in particular *S. aureus* including MRSA.

Fusidic acid is also active against *Streptococcus spp.*, *Corynebacterium minutissimum*, some *Neisseria spp.*, and certain *Clostridium spp.*

Resistance

In *S. aureus* two main types of resistance mechanisms have been characterized. The first is caused by mutations in the fusidic acid binding site of EF-G (*fusA*) and the other involves horizontal acquisition of determinants encoding *FusB* –type resistance determinants (*fusB* and *fusC*) that binds to EF-G.

Due to its unique molecular structure and distinct mode of action, target specific cross-resistance with other classes of antibacterial agents has not been detected.

Naturally resistant species

Most gram negative bacteria (including *Haemophilus influenza*, Enterobacteriaceae such as *Escherichia coli* and *Klebsiella pneumonia* and *Pseudomonas spp.*) are inherently resistant to fusidic acid.

5.2 Pharmacokinetic properties

There are no data that accurately define the pharmacokinetics of Fucicort® following topical administration in human.

In vivo and *in vitro* studies suggest that there is only negligible systemic absorption of topically administered fusidic acid. *In vitro* studies show that fusidic acid can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to fusidic acid and the condition of the skin. Fusidic acid is excreted mainly in the bile with little excreted in the urine.

The concentration of fusidic acid achieved in the skin is well above the minimum inhibitory concentration (MIC) required for sensitive *S. aureus* strains.

As there is only negligible systemic absorption of topically administered fusidic acid, the amount of fusidic acid likely to be distributed, biotransformed and eliminated from the systemic circulation following appropriate topical application is therefore of little clinical significance.

Betamethasone valerate is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Occlusion of the treated area under plastic material strongly increases the absorption. The amount absorbed is metabolized in the liver and excreted in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether (Cetomacrogol 1000)

Cetostearyl alcohol

Chlorocresol

Liquid paraffin

Monobasic sodium phosphate dehydrate

White soft paraffin

All-*rac*- α -tocopherol

Sodium hydroxide

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 30°C

6.5 Nature and contents of container

15 g

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local legislation.

7 MEDICINE CLASSIFICATION

Prescription Medicine

8 SPONSOR

LEO Pharma Ltd
Auckland
New Zealand
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9 DATE OF FIRST APPROVAL

31 July 1986

10 DATE OF REVISION OF TEXT

15 May 2023

Summary table of changes

Section changed	Summary of new information
4.4	Updated rebound effects under section 4.4
4.4	Updated HPA axis suppression under Section 4.4
4.8	Updated HPA axis suppression under Section 4.8

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