NEW ZEALAND DATA SHEET
FUCICORT®

NAME OF MEDICINE
FUCICORT®
Fusidic acid 20mg
Betamethasone as valerate 1mg

PRESENTATION
FUCICORT® is a white cream containing Fusidic acid BP 20mg and Betamethasone valerate 1mg in 1g of water miscible base.

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

DOSAGE AND 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.

CONTRAINDICATIONS
i. Hypersensitivity to fusidic acid/sodium fusidate, betamethasone valerate or to any of the excipients (see FURTHER INFORMATION for a list of excipients).
ii. Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment.
iii. Systemic fungal infection.
iv. Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy.
v. Perioral dermatitis and rosacea.
vi. Ulcerative conditions.
vii. The use of fluorinated steroids is contraindicated on the face.
WARNINGS & PRECAUTIONS

(a) Long-term continuous topical therapy with FUCICORT® should be avoided.

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

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

(d) Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with FUCICORT®. Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids, especially under occlusion with weekly doses of over 30g. Routine steroid precautions must be observed particularly if the patient is stressed—(e.g. following surgery).

(e) Babies and children up to four years should not be treated with dermal steroids for longer than three weeks. In infants the napkin may act as an occlusive dressing and increase absorption. Topical corticosteroid-induced HPA axis suppression and Cushing’s syndrome is more likely to occur in infants and children. Avoid large amounts, occlusion and prolonged treatment.

(f) Prolonged use on flexures and intertriginous areas is undesirable.

(g) 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.

(h) 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.

(i) FUCICORT® contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions.

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.

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

ADVERSE 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 ≥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
Uncommon: Hypersensitivity

Skin and subcutaneous tissue disorders
Uncommon: dermatitis contact, eczema (condition aggravated), skin burning sensation, pruritus, dry skin
Rare: erythema, urticaria, rash (including rash erythematous and rash generalised)

General disorders and administration site conditions
Uncommon: application site pain or irritation
Rare: application site swelling or vesicles
Systemic undesirable class effects of corticosteroids like betamethasone valerate include adrenal suppression especially during prolonged topical administration (see WARNINGS AND PRECAUTIONS).

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 WARNINGS AND PRECAUTIONS).

Dermatological undesirable class effects of potent corticosteroids include: Atrophy, dermatitis (incl. dermatitis contact and dermatitis acneiform), perioral dermatitis, skin striae, telangiectasia, rosacea, erythema, hypertrichosis, hyperhydrosis, and depigmentation. 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.

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

OVERDOSAGE
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.

PHARMACEUTICAL PRECAUTIONS
Store at or below 30°C.

FURTHER INFORMATION

PHARMACOKINETICS
Betamethasone valerate is absorbed through the skin when applied topically. Fusidic acid penetrates normal or inflamed skin and achieves bactericidal concentrations down to the lower corium within 16 hours.

OTHER
The cream base is non-staining and contains no lanoline or other fatty or known allergenic substances.
Excipients: Macrogol cetostearyl ether (Cetomacrogol 1000), cetostearyl alcohol, chlorocresol, liquid paraffin, monobasic sodium phosphate dehydrate, purified water, white soft paraffin, all-rac-α-tocopherol

PACKAGE QUANTITIES
15g

MEDICINE CLASSIFICATION
Prescription Medicine

SPONSOR DETAILS
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