SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fucicort® Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fucicort cream contains Fusidic acid 2% and Betamethasone (as valerate) 0.1%.

Excipients with known effect:
Cetostearyl alcohol and Chlorocresol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.
A white cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of eczematous dermatoses when secondary bacterial infection is confirmed.

4.2 Posology and method of administration

Posology

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

Method of administration

Cutaneous use.

4.3 Contraindications

Hypersensitivity to fusidic acid/sodium fusidate, betamethasone valerate or to any of the excipients listed in section 6.1.

Due to the content of corticosteroid, Fucicort is contraindicated in the following conditions:

Systemic fungal infections.

Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment (see section 4.4).

Skin manifestations in relation to tuberculosis or syphilis, either untreated or uncontrolled by appropriate therapy.

Perioral dermatitis and rosacea.

4.4 Special warnings and precautions for use

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

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).

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 corticosteroids.

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids.

Fucicort should be used with care in children as paediatric patients may demonstrate greater susceptibility to topical corticosteroids-induced HPA axis suppression and Cushing's syndrome than adult patients. Avoid large amounts, occlusion and prolonged treatment (see section 4.8).

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

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 (see section 4.3).

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

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.

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

4.5 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.

4.6 Fertility, pregnancy and lactation

Pregnancy

Fusidic acid:

No effects during pregnancy are anticipated, since systemic exposure to fusidic acid is negligible. Studies in animals have not shown teratogenic effects with fusidic acid. Limited studies in animals have shown negligible systemic absorption of topical fusidic acid.

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/foetal abnormalities (see section 5.3). Fucicort should not be used during pregnancy unless clearly necessary.

Breast-feeding

No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of the topically applied fusidic acid and betamethasone valerate to a limited area of skin of breast-feeding woman is negligible. Fucicort can be used during breast-feeding but should not be applied on the breasts to avoid accidental ingestion by the infant.

Fertility

There are no clinical studies with Fucicort regarding fertility.

4.7 Effects on ability to drive and use machines

Fucicort has no or negligible influence on the ability to drive or to 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 ≥ 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

Not known (cannot be estimated from the available data)

Immune system disorders	
Uncommon: (≥1/1,000 and <1/100)	Hypersensitivity
Eye disorder	
Not known	Vision, blurred*
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Dermatitis contact Eczema (condition aggravated) Skin burning sensation Pruritus Dry skin
Rare: (≥1/10,000 and <1/1,000)	Erythema Urticaria Rash (including rash erythematous and rash generalised)
Not known	Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules*
General disorders and administration site conditions	
Uncommon: (≥1/1,000 and <1/100)	Application site pain Application site irritation
Rare: (≥1/10,000 and <1/1,000)	Application site swelling Application site vesicles

*See also section 4.4

Systemic undesirable class effects of corticosteroids like betamethasone valerate include adrenal suppression especially during prolonged topical administration (see section 4.4).

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

Dermatological undesirable class effects of potent corticosteroids include: Atrophy, dermatitis (including dermatitis contact and dermatitis acneiform), perioral dermatitis, skin striae, telangiectasia, rosacea, erythema, hypertrichosis, hyperhidrosis 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 table above.

Paediatric population
The observed safety profile is similar in children and adults (see section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: D07CC01, corticosteroids (Group III) and antibiotics in combination, for external use.

Betamethasone is classed as a potent corticosteroid.

Fucicort cream combines the well-known anti-inflammatory and antipruritic effects of betamethasone with the potent topical antibacterial action of fusidic acid.
Betamethasone valerate is a topical steroid rapidly effective in those inflammatory dermatoses which normally respond to this form of therapy.

More refractory conditions can often be treated successfully. When applied topically, fusidic acid is effective against *Staphylococcus aureus,* Streptococci, Corynebacteria, Neisseria and certain Clostridia and Bacteroides.

Concentrations of 0.03 to 0.12 microgram per ml inhibit nearly all strains of *S. aureus*. The antibacterial activity of fusidic acid is not diminished in the presence of betamethasone.

5.2 Pharmacokinetic properties

There are no data which define the pharmacokinetics of Fucicort cream, following topical administration in man.

However, *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.

Betamethasone is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Betamethasone is metabolised largely in the liver but also to a limited extent in the kidneys, and the inactive metabolites are excreted with the urine.

5.3 Preclinical safety data

Studies of corticosteroids in animals have shown reproductive toxicity (e.g. cleft palate, skeletal malformations, low birth weight).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Cetostearyl alcohol
Liquid paraffin
Macrogol cetostearyl ether
Sodium dihydrogen phosphate dihydrate
Chlorocresol
Sodium hydroxide
Purified water
All-rac-α-tocopherol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

After first opening of the container: 3 months.

6.4 Special precautions for storage

Store below 30°C.
For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Aluminium tube of 15 g.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel.

8. MARKETING AUTHORISATION NUMBER

056-30-26527-00

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