SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

Fucibet Cream, 20 mg/1 mg/g

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains:

Fusidic acid hemihydrate equivalent to fusidic acid anhydrous 20 mg

Betamethasone valerate equivalent to betamethasone1 mg

Excipient with known effect

Chlorocresol: 0,1 % m/v as a preservative

Cetostearyl alcohol: 72 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

A white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fucibet Cream is indicated for the short-term treatment (2 weeks) of eczematous dermatoses colonised by bacteria sensitive to fusidic acid.

Concentrations of fusidic acid between 0,03 - 0,12 mcg/ml inhibit almost all strains of *Staphylococcus aureus*. Topical application of fusidic acid is also effective against, *Neisseria*, *Streptococci*, *Corynebacteria*, certain *Clostridia* and *Bacteroides*.

4.2 Posology and method of administration

Posology

Adults and children:

Fucibet Cream should be thinly applied 2 - 3 times daily and massaged gently into the affected areas.

A treatment period of 2 weeks is normally sufficient.

Paediatric population

Fucibet Cream contraindicated in children under the age of 2 years (see section 4.3).

Method of administration

For cutaneous use only.

4.3 Contraindications

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

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

- Systemic fungal infections.
- Primary bacterial, fungal or viral skin infections either untreated or uncontrolled by appropriate treatment (see section 4.4).
- Rosacea and perioral dermatitis.
- Vaccination reactions.
- In skin manifestations in relation to tuberculosis or syphilis, either untreated or uncontrolled by appropriate treatment.
- Patients with ulcus cruris.
- Under occlusion or in intertrigenous lesions.
- Pregnant women (see section 4.6).
- Children under the age of 2 years.

4.4 Special warnings and precautions for use

Hypersensitivity

Hypersensitivity and allergic reactions may occur following topical application of Fucibet

Cream.

Prolonged use, risk of resistance and masking of infection

Prolonged use may cause skin atrophy, including skin striae, thinning and dilation of superficial blood vessels, especially when occlusion is employed.

Fucibet Cream should not be used for prolonged periods on the face.

The use of topical fusidic acid has been reported to cause bacterial resistance; therefore, prolonged application should be avoided to reduce the risk of contact sensitisation and the development of antibiotic resistance from occurring.

Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of clinical improvement, as corticosteroids may mask hypersensitivity and, in this situation, occult extension of the infection may occur. 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.

Systemic absorption and endocrine effects

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

Caution should be exercised in the treatment of large skin areas, the face, and intertriginous skin areas. Not more than 30 % of the skin area should be treated per application.

As with other topical corticosteroids, sufficient systemic absorption to produce hypercorticism can occur with used, prolonged or extensive use, especially in infants and children wherein occlusive dressings are such as napkins.

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

Use near the eyes and visual disturbance

Due to the content of corticosteroid, Fucibet Cream should be used with care near the eyes. Contact with the eyes should be avoided (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.

Local skin conditions where use should be avoided

The use of Fucibet Cream in the case of skin atrophy, cutaneous ulcers, acne vulgaris, fragility of skin veins as well as perianal and genital pruritis should be avoided due to the content of corticosteroid.

The use of Fucibet Cream should also be avoided in open wounds and mucous membranes.

Increased susceptibility to infection

Due to the content of corticosteroid having immunosuppressant effect, Fucibet Cream 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).

Topical steroid withdrawal syndrome

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 advise is recommended in these cases or other treatment options should be considered.

Risk of fire and severe burns

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.

Excipients with known effect

Fucibet Cream contains cetostearyl alcohol and chlorocresol.

- Cetostearyl alcohol may cause local skin reactions (e.g., contact dermatitis).

- Chlorocresol may cause allergic reactions.

Paediatric population

Long term continuous topical therapy should be avoided., especially in children older than 2 years of age as adrenal suppression can occur even without occlusion. Occlusive dressing increases the absorption of betamethasone and should not be used.

Fucibet Cream 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.

4.5 Interaction with other medicines 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

Fucibet Cream is contraindicated in pregnant women.

Fusidic acid:

There is evidence to suggest that when fusidic acid is given systemically, fusidic acid can penetrate the placental barrier.
However, for topical use, 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 of corticosteroids in animals have shown reproductive toxicity (e.g. cleft palate, skeletal malformations, low birth (see section 5.3). Therefore, there is a risk for such effects in the human foetus.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the topically applied fusidic acid and betamethasone valerate to a limited area of skin of the breast-

feeding woman is negligible. Fucibet Cream can be used during breastfeeding but should not be applied on the breasts to avoid accidental ingestion by the infant.

Fertility

There are no clinical studies with Fucibet Cream regarding effect on fertility.

4.7 Effects on ability to drive and use machines

Fucibet Cream 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.

a. Summary of the safety profile

The most frequently reported adverse reaction during treatment is pruritus.

Undesirable effects are listed by MedDRA SOC (System Organ Class) 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 (≥ 1 000 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)

b. Tabulated list of adverse reactions

MedDRA System Organ Class	**Frequency**	**Side effects**
Infections and infestations:	Uncommon	Otitis externa, urinary tract infection
Immune system disorders	Uncommon	Hypersensitivity
Eye disorder	Not known	Vision, blurred*

Skin and subcutaneous tissue disorders	Uncommon	Dermatitis contact, eczema (condition aggravated), swollen hand, skin irritation, skin burning sensation, pruritus, skin dryness, smarting of atopic dermatitis, scalp dermatitis
	Rare	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	Sore throat, flu-like illness, activation of a herpes simplex infection, application site pain, application site irritation
	Rare	Application site swelling, application site vesicles

*See also section 4.4

c. Description of selected adverse reactions

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 Fucibet Cream 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 medicine is important. It allows

continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Reporting can also be done directly to Adcock Ingram Limited at Adcock.aereports@adcock.com.

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 Fucibet Cream 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

Category and Class: A 13.4.1 Corticosteroids with or without anti-infective agents.

Pharmacotherapeutic group: D 07 CC 01, corticosteroids (Group III) and antibiotics in combination, for external use, ATC code: D 07 CC 01.

Betamethasone is classed as a potent corticosteroid.

Fucibet 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.

Fusidic acid exhibits an antibacterial action when applied topically by inhibiting bacterial synthesis mainly against gram positive bacteria. These degenerative changes breakdown the cell wall structure and lead to the death of the micro-organisms.

More refractory conditions can often be treated successfully. When applied topically, fusidic acid is effective against *Staphyloccus 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 Fucibet Cream, following topical administration in man.

Absorption
Betamethasone is absorbed following topical administration. The degree of absorption is dependent on factors such as the site of application and the skin condition.

Distribution
Fusidic acid is widely distributed into tissues.
In vitro studies have shown that fucidic acid penetrates human skin. The degree of penetration depends on factors such as skin condition and duration of exposure to skin.
Up to 2,5 % of the applied dose has been shown to cross intact human skin *in-vitro*, and up to 10 % may cross damaged skin.

Biotransformation
Metabolism primarily takes place in the liver, with a little metabolism occurring in the kidneys and the inactive metabolites excreted in the urine.

Elimination
Excretion of fusidic acid is mainly in bile and little is excreted in urine or removed by haemodialysis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Chlorocresol
Liquid paraffin

Macrogol cetostearyl ether

Purified water

Sodium dihydrogen phosphate dihydrate (for pH-adjustment)
Sodium hydroxide (pH adjusting agent)
White soft paraffin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened tube: 3 years

After first opening of the tube: 3 months

6.4 Special precautions for storage

Store at or below 30 °C.
For storage conditions after first opening of the tube, see section 6.3
Keep well closed.

Store in outer carton until use.

6.5 Nature and contents of container

Fucibet Cream is packaged in aluminium tubes with membrane and a re-closable polyethylene screw cap with a spike. The aluminium tubes are lacquered inside with a coating on the entire surface of epoxy phenol and with a sealant lacquer coating of acrylic acid ester copolymer in the fold area.
The pack sizes are 5 g, 15 g, 30 g and 60 g.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and handling
No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road,

Erand Gardens,
Midrand, 1685.
Customer Care: 0860 ADCOCK/ 232625

8 REGISTRATION NUMBER

45/13.4.1/0678

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05 June 2014

10 DATE OF REVISION OF THE TEXT

11 August 2026