Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucibet 20mg/g + 1mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fusidic acid 20mg/g and betamethasone 1mg/g (as betamethasone valerate).

Excipients: contains cetostearyl alcohol and chlorocresol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Product imported from UK.
A white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Use in inflammatory dermatoses where bacterial infection is present or likely to occur.

4.2 Posology and method of administration

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

4.3 Contraindications

Known hypersensitivity to fusidic acid/sodium fusidate, betamethasone valerate or any of the excipients.

Due to the content of corticosteroid, Fucibet® is contraindicated in the following conditions: skin infections primarily caused by bacteria, fungi or virus (such as herpes or varicella), skin manifestations in relation to tuberculosis or syphilis, perioral dermatitis and rosacea.

4.4 Special warnings and precautions for use

Long-term continuous topical therapy should be avoided, particularly in infants and children. Adrenal suppression can occur even without occlusion. Atrophic changes may occur on the face, and to a lesser degree in other parts of the body, after prolonged treatment with potent topical steroids. Caution should be exercised if Fucibet cream is used near the eye. Glaucoma might result if the preparation enters the eye. Systemic chemotherapy is required if bacterial infection persists.

Bacterial resistance has been reported to occur with the use of fusidic acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

The use of steroid-antibiotic combinations should be limited to 2 weeks as steroids may mask infections or hypersensitivity reactions.

Due to the content of corticosteroid, use of Fucibet should be avoided in the following conditions: Atrophic skin, cutaneous ulcers, acne vulgaris and in flexures/genital area.

Fucibet must be used with caution in the treatment of large areas of the body and face. Contact with open wounds and mucous membranes should be avoided.

Fucibet Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy
Safety for use of Fucibet during human pregnancy has not been established. Studies in animals have not shown teratogenic effects with fusidic acid but studies with corticosteroids have shown teratogenic effects. The potential risk for humans is unknown. Fucibet should not be used during pregnancy unless clearly necessary.

Lactation
No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding woman to fusidic acid and betamethasone is negligible following topical application to a limited area of skin. Fucibet can be used during breast-feeding.
Fucibet should not be used on the breast by breast-feeding women.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

The most frequently reported undesirable effects are various symptoms of application site irritation. Allergic reactions have been reported.

Based on clinical study data for Fucibet® approximately 3% of patients can be expected to experience an undesirable effect. Transient skin irritation, stinging or burning sensation, pruritus, rash and worsening of eczema were uncommon.

Immune system disorders
Very rare:
Allergic reaction

Skin and subcutaneous tissue disorders
Uncommon:
Eczema aggravation
Urticaria
Contact dermatitis
Dry skin

Rash
Skin irritation
Skin burning sensation
Skin stinging sensation
Pruritus
Erythema

Very rare:
Skin atrophy
Telangiectasia

Undesirable effects observed for corticosteroids include:
Skin atrophy, telangiectasia and skin striae, especially during prolonged application, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, systemic activity such as glaucoma and adrenocortical suppression.

4.9 Overdose

Excessive prolonged use of topical corticosteroids may suppress the pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases symptomatic treatment is indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D07CC01

Fucibet Cream combines the potent topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of betamethasone valerate.

Fusidic acid and its salts exhibit fat and water solubility properties with strong surface activity, and show unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg/ml inhibit nearly all strains of *Staphylococcus aureus*. Topical Fucidin is also active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

Betamethasone valerate is a potent topical corticosteroid rapidly effective in those inflammatory dermatoses which normally respond to this form of therapy.

5.2 Pharmacokinetic properties

There are no data which define the pharmacokinetics of Fucibet 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

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether
Cetostearyl alcohol
Chlorocresol
Liquid paraffin
Sodium dihydrogen phosphate
White soft paraffin
Purified water
all-*rac*-α-tocopherol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on outer package of the product on the market in the country of origin.
After first opening: 3 months

6.4 Special precautions for storage

Do not store above 30˚C.

6.5 Nature and contents of container

Aluminium tube with a white polyethylene screw cap.
Pack size: 30g

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/183/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th January 2013

10 DATE OF REVISION OF THE TEXT

May 2013