1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

Summary of Product Characteristics (SmPC)

1. Name of the medicinal product
Fusibact B Cream

2. Qualitative and quantitative composition
Fusibact B Cream contains Fusidic acid 2% and Betamethasone 0.1% (as Valerate).
Excipients with known effect: Contains Cetostearyl alcohol and Chlorocresol.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Cream
White, smooth cream with characteristic odor, free from grit or lumps.

4. Clinical particulars
4.1 Therapeutic indications
Fusibact B Cream is indicated for the treatment of eczematous dermatoses including atopic eczema, infantile eczema, discoid eczema, stasis eczema, contact eczema and seborrhoeic eczema when secondary bacterial infection is confirmed or suspected.

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 Fusibact B Cream can be enhanced by occlusion with polythene film. Overnight occlusion is usually adequate.

Method of administration

Cutaneous use.

4.3 Contraindications
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
Due to the content of corticosteroid preparations, fusidic acid/betamethasone cream 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 should be avoided.

Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fusibatc-B

Due to the content of corticosteroid, Fucibet should be used with care near the eyes. Avoid getting Fucibet 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.

Fusibatc-B 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 Fusibatc-B 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.

Bacterial resistance has been reported to occur with the use of fusidic acid applied topically. As with all antibiotics, extended or recurrent application 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, Fusibact-B 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).

Fucibet-B 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 continuous or inappropriate 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.

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).

Fusibact B Cream 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 the breastfeeding woman is negligible. Fusibact B Cream 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 Fusibact B regarding fertility.

4.7 Effects on ability to drive and use machines
Fusibact B Cream 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 pruritis.

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 intraocular pressure, glaucoma and 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 fusidic acid/betamethasone cream described in the frequency table above.

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

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 3 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 Fusibact B 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
Pharmacotherapeutic group: D07CC01, corticosteroids (Group III) and antibiotics in combination, for external use, ATC code: D07CC01. Fucibet B 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 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 Fusibact B 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 metabolized 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, and low birth weight).

6. Pharmaceutical particulars
6.1 List of excipients
Chlorocresol
Vitamin E Acetate (alpha-Tocopherol)
Cetomacrogol 1000
Cetostearyl Alcohol
White Soft Paraffin
Liquid Paraffin
Sodium Dihydrogen Phosphate Anhydrous
Sodium hydroxide
Purified Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Unopened container: 24 month(s)
After first opening: 3 month(s)

6.4 Special precautions for storage
Do not store above 30°C.

6.5 Nature and contents of container
Aluminum tube of 15g and 30 g
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

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8. Marketing authorisation number(s)

B4-7661

9. Date of first authorisation/renewal of the authorisation

31-10-2017

10. Date of revision of the text

Aug 2022