SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains 20 mg fusidic acid and 1 mg betamethasone corresponding to 1,214 mg betamethasone valerate.

Excipients with known effect: Contains cetostearyl alcohol 72 mg/g and chlorocresol 1 mg/g.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

White to off white, smooth, homogeneous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream is indicated for the treatment of eczematous dermatoses including atopic eczema, infantile eczema (children of 1 year and over), 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 single treatment course should not normally exceed 2 weeks.

Method of administration

For cutaneous use.

A small quantity should be applied thinly to the affected area twice daily until a satisfactory response is obtained. In the more resistant lesions the effect of Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream can be enhanced by occlusion with polyethylene film. Overnight occlusion is usually adequate.

Hands should be washed before and after using this medicine to avoid cross-infection and ocular absorption.

Care should be taken to avoid the cream coming into direct contact with the eyes to avoid ocular absorption of corticosteroid (see section 4.4) and conjunctival irritation from fusidic acid

Adults and children:

In adults as in children, the method of fingertip unit can be used to better specify the quantity of cream applied to a given surface.

One fingertip unit is defined as a line from the tip of an adult index finger to the first crease.

The usual number of fingertip units needed to cover different parts of the body is described hereafter. When using the cream in children, an adult finger should still be used to measure out the fingertip unit.

For an adult	
Site of application	Usual number of finger tip units of cream
Face and neck	2½
Back of the trunk	7
Front of the trunk	7
One arm (not including the hand)	3
One hand (both sides)	1
One leg (not including the foot)-	6
One foot	2

For a child from 1 to 10 years			
	Usual number of finger tip units of cream		
Site of application	For a child aged 1-2 years	For a child aged 3-5 years	For a child aged 6-10 years
Face and neck	1½	1½	2
One arm and hand	1½	2	2½
One leg and foot	2	3	4½
Front of the trunk	2	3	3½
Back of the trunk including the buttocks	3	3½	5

4.3 Contraindications

Hypersensitivity to the actives substances or to any of the excipients listed in section 6.1.

As with other topical corticosteroid preparations, Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream is contraindicated in infants under one year of age and in the following conditions: , skin lesions of viral, fungal or bacterial origin (such as herpes or varicella), skin manifestations in relation to tuberculosis or syphilis, acne vulgaris, perioral dermatitis and rosacea.

4.4 Special warnings and precautions for use

The label will state strong steroid.

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

Due to the content of corticosteroid, this medicine should be used with care near the eyes. Avoid getting this medicine into the eyes (see section 4.8).

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur with or without occlusions following systemic absorption of topical corticosteroids.

This medicine should be used with care in children as pediatric patients may be more susceptible to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than adult patients (see section 4.8).

Long-term continuous topical therapy should be avoided, particularly in children. Adrenal suppression can occur even without occlusion. Cushing syndrome may occur as a potential risk in line with adrenal suppression. 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 Fusidic acid/Betamethasone 20 mg/g + 1 mg/g 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 applied topically. As with all topical antibiotics, extended or recurrent application may increase the risk of developing antibiotic resistance.

Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement to avoid propagation of subclinical infection due to masking by the steroid. Similarly, steroids may also mask hypersensitivity reactions.

Due to the immunosuppressant effect of corticosteroids, this medicine may be associated with increased susceptibility to infection, aggravation of existing infection, and activation of latent infection. It is advised to switch to systemic therapy if infection cannot be controlled with topical treatment (see section 4.3).

This medicine contains a corticosteroid it is not recommended in the following conditions: atrophic skin, cutaneous ulcer, acne vulgaris, fragile skin veins and perianal and genital pruritus. Contact with open wounds and mucous membranes should be avoided. As with all corticosteroids, prolonged use on the face should be avoided.

Visual disturbance

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.

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.

Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions.

Applicable guidance on the appropriate use of antibacterial agents should be adhered to.

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 Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream during 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.

Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream should not be used during pregnancy unless clearly necessary.

Breast-feeding

No effects on the infant are anticipated since the systemic exposure of the breast-feeding woman to fusidic acid and betamethasone is negligible. Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream can be used when breast-feeding but should not be used on the breast.

Fertility

Non-clinical studies with fusidic acid showed no effects on fertility, but betamethasone has been reported to impact fertility in rats.

There are no clinical studies with Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream regarding fertility.

4.7 Effects on ability to drive and use machines

Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream has no or negligible influence on the ability to drive or to use machines.

4.8 Undesirable effects

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

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported.

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
Not known
Allergic reaction

Skin and subcutaneous tissue disorders
Uncommon
Skin irritation
Skin burning sensation
Pruritus
Eczema aggravated
Skin stinging sensation
Erythema
Rare
Urticaria
Dry skin
Not known (cannot be estimated from available data)
Contact Dermatitis
Rash
Telangiectasia
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. (see section 4.4)

Eye disorders
Not known
Vision, blurred (see also section 4.4)

Class effect

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

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. Healthcare professionals are asked to report any suspected adverse reactions via [To be completed nationally].

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

Pharmacotherapeutic group: Corticosteroids, potent, combination with antibiotic,

ATC code: D07C C01.

Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream combines the well-known anti-inflammatory and antipruritic effects of betamethasone with the potent topical antibacterial action of fusidic acid. Betamethasone 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 Fusidic acid/Betamethasone 20 mg/g + 1 mg/g 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 pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether

Cetostearyl alcohol

Chlorocresol

Liquid paraffin

Sodium dihydrogen phosphate dihydrate

White soft paraffin

All-rac-α-tocopherol

Purified water

Sodium hydroxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 36 months.

After first opening: 6 months.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

Aluminium tubes of 5 gram, 15 gram, 30 gram, and 60 grams.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pharmascience International Ltd

Lampousas 1

1095 Nicosia

Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 46740/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/07/2021

10 DATE OF REVISION OF THE TEXT

28/08/2024