SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fucidin H cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fucidin H cream contains fusidic acid Ph.Eur.2% and hydrocortisone acetate Ph.Eur.1%.
Excipients with known effect
Butyl hydroxyanisole E320 (40 microgram/g), cetyl alcohol (111 mg/g), potassium sorbate E202 (2.7 mg/g) and polysorbate 60 (56 mg/g).
For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Cream for topical administration

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fucidin H cream is indicated in eczema and dermatitis with secondary bacterial infections, including atopic eczema, primary irritant dermatitis and allergic and seborrhoeic dermatitis where the organisms responsible are known to be or believed to be sensitive to fusidic acid.

4.2 Posology and method of administration

Adults and Children:
Uncovered lesions - 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.
Covered lesions - less frequent applications may be adequate.

4.3 Contraindications

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

Due to the content of corticosteroid, Fucidin H cream is contraindicated in the following conditions:
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, 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 Fucidin H cream should be avoided.

Depending on the application site, possible systemic absorption of hydrocortisone acetate should always be considered during treatment with Fucidin H cream.

Due to the content of corticosteroid, Fucidin H cream should be used with care near the eyes. Avoid getting Fucidin H cream 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 with or without occlusions following systemic absorption of topical corticosteroids.

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

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 hydrocortisone acetate 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. Steroid antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement.

Due to the immunosuppressant effect of corticosteroids, Fucidin H 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

therapy if infection cannot be controlled with topical treatment (see section 4.3).

As Fucidin H cream 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.

Fucidin H cream contains butyl hydroxyanisole, cetyl alcohol and potassium sorbate. These excipients may cause local skin reactions (e.g. contact dermatitis). Butyl hydroxyanisole may also cause irritation to the eyes and mucous membranes. Fucidin H cream contains polysorbate 60. Polysorbates can 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 advise is recommended in these cases or other treatment options should be considered.
The label will state mild steroid.

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.

Hydrocortisone acetate:
A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicates no malformative nor feto/neonatal toxicity of corticosteroids.

Fucidin H cream can be used during pregnancy if clinically needed. However, based on a general knowledge about systemic corticosteroids, caution should be exercised when using Fucidin H cream during pregnancy.

Breastfeeding
No effects on the breastfed new-born/infant are anticipated since the systemic exposure of topically applied fusidic acid/hydrocortisone acetate to a limited area of skin of the breastfeeding woman is negligible.

Fucidin H cream can be used during breastfeeding but it is recommended to avoid applying Fucidin H cream on the breast.

Fertility
There are no clinical studies with Fucidin H cream regarding fertility.

4.7 Effects on ability to drive and use machines

Fucidin H 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 adverse reactions is based on a pooled analysis of data from clinical studies and spontaneous reporting.

The most frequently reported adverse reactions during treatment are application site reactions including pruritus, burning and irritation.
Adverse reactions are listed by MedDRA system organ class (SOC) and the individual adverse reactions 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 disorders	
Not known	Vision, blurred*
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Dermatitis contact Eczema (condition aggravated) Rash

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	
Common: (≥1/1,00 and <1/10)	Application site reaction (incl. pruritus, burning and irritation)

* See also section 4.4

Systemic undesirable effects

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

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

Dermatological undesirable class effects of mild corticosteroids like hydrocortisone include: Atrophy, dermatitis (incl. dermatitis contact, dermatitis acneiform and perioral dermatitis), skin striae, telangiectasia, rosacea, erythema, depigmentation, hypertrichosis and hyperhidrosis. Ecchymosis may also occur with prolonged use of topical corticosteroids.

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 Fucidin H 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: Hydrocortisone and antibiotics, ATC code: D 07 CA 01

Hydrocortisone is classed as a mild corticosteroid.

Fucidin H cream combines the potent topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of hydrocortisone. Concentrations of 0.03 - 0.12 micrograms fusidic acid per ml inhibit nearly all strains of *Staphylococcus aureus.* Topical application of fusidic acid is also effective against streptococci, corynebacteria, neisseria and certain clostridia.

5.2 Pharmacokinetic properties

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

However, i*n 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.

Hydrocortisone is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Absorbed hydrocortisone is extensively metabolised and rapidly eliminated in 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 SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin, potassium sorbate, polysorbate 60, white soft paraffin, all-rac-α-tocopherol, purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 3 years

After first opening of container: 3 months

6.4 Special precautions for storage

Do not store above 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 3 gram, 5 gram, 10 gram, 15 gram, 25 gram, 30 gram and 60 gram.

6.6 Instructions for Use/Handling

None.

7 MARKETING AUTHORISATION HOLDER

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UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00043/0093

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/11/1983
Renewal: 20/08/2010

10 DATE OF REVISION OF THE TEXT

28/05/2026