SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FUCITEC(FUCIDIC ACID) 2.0%W/W CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Each gram contains 20 mg fusidic acid.

Excipients: Each gram contains 0.5 mg butylhydroxyanisole, 50 mg cetyl alcohol and 1 mg potassium sorbate.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

FUCİTEC is indicated in the treatment skin infections caused by staphylococcus, streptococcus, propionibacterium acnes, corynebacterium minutissimum and other sensitive strains to FUCİTEC.

Main indications are; infected burns and wounds, impetigo, infected eczema, folliculitis, infected acne, infected abscess, acne vulgaris, paronychia, sycosis barbae, hidradenitis and erythrasma.

4.2 Posology and method of administration

Posology/frequency and period:

Topically applied to lesion two or three times a day according to doctors recommendation. After administration it can be covered or hold as open

Administration:

Topically applied to skin.

Additional information for special population:

Kidney/Liver failure: There is not a study of topical usage of FUCİTEC for patients with kidney/liver failure.

Paediatric population:

There is not a restriction of use for paediatric patients

Geriatric population:

There is not a restriction of use for geriatric patients

4.3 Contraindications

It is contraindicated for hypersensitivity to the active substance or to fusidic acid, salt sor any of excipients. Should not be used for the infections that caused by resistant organisms like *Pseudomonas aeruginosa*.

4.4 Special warnings and precautions for use

It can cause irritation to the eyes and mucous membranes, therefore be used with care when applied in the proximity of the eyes.

As with all antibiotics, extended or recurrent use may increase the risk of developing contact sensitisation and antibiotic resistance.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction has been observed.

4.6 Fertility, pregnancy and lactation

General recommendation

Pregnancy category: B

Women of childbearing potential / Contraception in females

Animal studies, have not been shown direct or indirect adverse effects related to pregnancy/ embryonic/ foetal growth / birth or growth.

Should only be carefully administered for pregnants.

Lactation

There is no information on the excretion of FUCİTEC in milk. It should only be used when the potential benefits outweigh the possible risks of treatment by physician.

Fertility

There are no data regarding fertility.

4.7 Effects on ability to drive and use machines

It has no or negligible influence on the ability to drive or 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); unknown(not able to estimate with currrent data)

Immune system disorders

Unknown: allergic reactions

Dermatological disorders

Uncommon: exanthem, skin irritation, pruritus, burning and stinging, erythema, dry skin

Unknown: dermatitis contact, eczema, urticaria, angioedema

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

There are no information regarding overdose can occur for locally application of fusidic acid.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D06AX01

Pharmacotherapeutic group: Other antibiotics (topically used)

FUCİTEC's active ingredient fusidic acid is; an antibiotic which is obtained from *Fucudium cuccineum* culture and a potent antibacterial agent for many of gram-positive organisms.

Fusidic acid inhibits bacterial protein synthesis by blocking amino acid transfers from aminoacyl-tRNA to proteins.

Staphylococcus which are resistant to penicillin and other antibiotics are sensitive to fusidic acid.

Therapeutical effect of the of topically applied fusidic acid is partially related to antibacterial effect on the organisms which causes skin infections, and partially sourced from penetration ability from intact skin.

5.2 Pharmacokinetic properties

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.

Elimination:

Fusidic acid is excreted mainly in the bile with little excreted in the urine.

5.3 Preclinical safety data

No data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole

Cetyl alcohol

Liquid paraffin

Polysorbate 60

Potassium sorbate

Purified water

Petrolatum (White Fanoline H) Soft paraffin

Glycerin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 30 °C, protect from direct sun light and heat.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

20 g aluminium lacquered tube with HDPE screwed cap with patient information leaflet in a carton box.

6.6 Special precautions for disposal <and other handling>

The unused products or waste materials should be destroyed in accordance with “The Regulation Regarding the control of Medical Wastes Published” and “The Regulation Regarding the Control of Packages and Package Wastes Published”.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Certificate No: 05345/07449/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Sep 23, 2020

10. DATE OF REVISION OF THE TEXT

September 2023