APPROVED PACKAGE INSERT

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

Fucibet Cream

COMPOSITION:

Each gram of cream contains:

Fusidic acid anhydrous 20 mg

Betamethasone (as valerate) 1 mg

Chlorocresol 0,1 % *m/v* as a preservative

List of excipients:

cetostearyl alcohol, liquid paraffin, macrogol cetostearyl ether, purified water, sodium dihydrogen phosphate dihydrate, white soft paraffin.

PHARMACOLOGICAL CLASSIFICATION:

A 13.4.1 Corticosteroids with or without anti-infective agents.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Fusidic acid exhibits an antibacterial action when applied topically by inhibiting bacterial synthesis mainly against gram positive bacteria. These degenerative changes breakdown the cell wall structure and lead to the death of the micro-organisms.

Betamethasone valerate is a steroid with anti- inflammatory properties.

Pharmacokinetic properties:

Fusidic acid is widely distributed into tissues.

In vitro studies have shown that fucidic acid penetrates human skin. The degree of penetration depends on factors such as skin condition and duration of exposure to skin.

Up to 2,5 % of the applied dose has been shown to cross intact human skin *in-vitro*, and up to 10 % may cross damaged skin.

Excretion of fusidic acid is mainly in bile and little is excreted in urine or removed by haemodialysis.

Betamethasone is absorbed following topical administration. The degree of absorption is dependent on factors such as the site of application and the skin condition.

Metabolism primarily takes place in the liver, with a little metabolism occurring in the kidneys and the inactive metabolites excreted in the urine.

INDICATIONS:

Fucibet Cream is indicated for the short term treatment (2 weeks) of eczematous dermatoses colonised by bacteria sensitive to fusidic acid.

Concentrations of fusidic acid between 0,03-0,12 mcg/ml inhibit almost all strains of *Staph. aureus.* Topical application of fusidic acid is also effective against, *Neisseria, Streptococci, Corynebacteria*, certain *Clostridia* and *Bacteroides.*

CONTRA-INDICATIONS:

Hypersensitivity to the active ingredients or excipients of **Fucibet Cream.**

Fucibet Cream is contra-indicated in the following conditions:

- primary bacterial, fungal or viral skin infections
- rosacea and perioral dermatitis
- vaccination reactions
- in skin manifestations in relation to tuberculosis or syphilis
- patients with ulcus cruris
- under occlusion or in intertrigenous lesions
- pregnant women
- children under the age of 2 years.

WARNINGS:

Extended or recurrent application may increase the risk of contact sensitisation and the development of antibiotic resistance.

Long term continuous topical therapy should be avoided, especially in children older than 2 years of age as adrenal suppression can occur even without occlusion. Occlusive dressing increase the absorption of betamethasone and should not be used.

Caution should be exercised in the treatment of large skin areas, the face, and intertrigenous skin areas. Not more than 30 % of the skin area should be treated per application.

Care should be taken when applying the cream near the eye, as glaucoma might result if the preparation enters the eye.

INTERACTIONS:

Fucibet Cream is not known to have any interactions.

PREGNANCY AND LACTATION:

Pregnancy:

Fucibet Cream is contraindicated in pregnant women. Topical application of corticosteroids to pregnant animals can result in foetal abnormalities such as cleft-palate and intra-uterine growth retardation. Therefore, there is a risk for such effects in the human foetus. There is evidence to suggest that when fusidic acid is given systemically, fusidic acid can penetrate the placental barrier.

Lactation

Safety in lactation has not been established.

The use of **Fucibet Cream** is not recommended for breastfeeding mothers.

When fusidic acid is given systemically, levels have been detected in breast milk, but with topical administration the possible amount of medicine is unlikely to affect the infant.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children:

Fucibet Cream should be thinly applied 2 - 3 times daily and massaged gently into the affected areas. A treatment period of 2 weeks is normally sufficient.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

Very common (≥ 1/10)

Common (≥ 1/100 and <1/10)

Uncommon (≥ 1 000 and < 1/100)

Rare (≥ 1/10 000 and <1/1 000)

Very rare (<1/10 000)

Hypersensitivity and allergic reactions may occur following topical application of **Fucibet Cream**. Prolonged use may cause skin atrophy, including skin striae, thinning and dilation of superficial blood vessels, especially when occlusion is employed. As with other topical corticosteroids, sufficient systemic absorption to produce hypercorticism can occur with prolonged or extensive use, especially in infants and children wherein occlusive dressings are used, such as napkins.
The use of **Fucibet Cream** can also cause teleangiectasia, steroid acne, folliculitis, hypertrichosis, hypopigmentation, allergic contact dermatitis and perioral dermatitis.

Infections and infestations:

Uncommon:

- Otitis externa, urinary tract infection.

Skin and subcutaneous tissue disorders:

Uncommon:

- Eczema aggravated, swollen hand.
- Skin dryness, smarting of atopic dermatitis.
- skin irritation.
- scalp dermatitis.
- pruritis.

General disorders and administrative site conditions:

Uncommon:

- Sore throat
- Flu-like illness
- Activation of a Herpes simplex infection

Special precautions:

Fucibet Cream should not be used for prolonged periods on the face. Caution should be exercised when using **Fucibet Cream** near the eye. Glaucoma might result if the preparation enters the eye.
The use of topical fusidic acid has been reported to cause bacterial resistance; therefore prolonged application should be avoided to reduce the risk of contact sensitisation and the development of antibiotic resistance from occurring.
Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of clinical improvement, as steroids may mask hypersensitivity and in this situation occult extension of the infection may occur due to masking of the corticosteroid.

The use of **Fucibet Cream** in the case of skin atrophy, cutaneous ulcers, acne vulgaris, fragility of skin veins as well as perianal and genital pruritis should be avoided due to the content of corticosteroid.

The use of **Fucibet Cream** should also be avoided in open wounds and mucous membranes.

Cetostearyl alcohol can provoke local skin irritations such as contact dermatitis.

Chlorocresol can provoke allergic reactions.

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

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdosage has not been known to occur.

IDENTIFICATION:
A white to off-white homogenous cream.

PRESENTATION:
Fucibet Cream is packaged in aluminium tubes with membrane and a reclosable polyethylene screw cap. The aluminium tubes are lacquered inside with a coating on the entire surface and with a sealant lacquer in the fold area. The pack sizes are 5 g, 15 g, 30 g & 60 g.

STORAGE INSTRUCTIONS:
Store at or below 25 °C.
Shelf life after opening is 3 months.
KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Keep well closed.
Store in outer carton until use.

REGISTRATION NUMBER:
45/13.4.1/0678

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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