

210.00 mm

140.00 mm

FUCYN Cream 2% w/w
(Fusidic acid)فیوسن ۲% کریم
(فیوسنک الہڈ)**FUCYN-B** Cream
(Fusidic acid + Betamethasone valerate)فیوسن بی کریم
(فیوسنک الہڈ + بیٹامیتھاسون وائلریٹ)**FUCYN-H** Cream
(Fusidic acid + Hydrocortisone acetate)فیوسن ایچ کریم
(فیوسنک الہڈ + ہائیڈروکورتیسون اسیٹریٹ)**COMPOSITION:****FUCYN Cream 2% w/w**

Each gram contains:

Fusidic acid20mg (2% w/w)

(BP Specifications)**FUCYN-B Cream**

Each gram contains:

Fusidic acid.....20mg

Betamethasone (as valerate).....1mg

(Innovator's specifications)**FUCYN-H Cream**

Each gram contains:

Fusidic acid 20mg

Hydrocortisone acetate10mg

(Innovator's specifications)**DESCRIPTION:**

Fusidic acid is a topical antibacterial agent used to prevent and treat mild to moderate skin infections caused by susceptible bacteria. An antibiotic isolated from the fermentation broth of *Fusidium coccineum*. It acts by inhibiting translocation during protein synthesis.

Betamethasone valerate is a synthetic glucocorticoid ester. It is the 17 -valerate ester of betamethasone. Betamethasone valerate is often used to treat mild eczema with good efficacy and lower incidence of steroid induced adverse effects due to its lower potency compared to other glucocorticoids.

Hydrocortisone acetate is a corticosteroid used to treat inflammatory and pruritic corticosteroid- responsive dermatoses and ulcerative colitis.

MECHANISM OF ACTION:

Fusidic acid is a potent antibacterial agent.

Fusidic acid and its salts show fat and water solubility and strong surface activity and exhibit unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg 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.

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. The antibacterial activity of fusidic acid is not diminished in the presence of betamethasone.

Hydrocortisone acetate is a corticosteroid. Topical corticosteroids share antiinflammatory, antipruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

INDICATIONS:

FUCYN Cream 2% w/w is indicated either alone or in combination with systemic therapy, in the treatment of primary and secondary skin infections caused by sensitive strains of *Staphylococcus aureus*, *Streptococcus spp* and *Corynebacterium minutissimum*. Primary skin infections that may be expected to

respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma; also such secondary skin infections as infected eczematoid dermatitis, infected contact dermatitis and infected cuts/abrasions. Fucyn cream is an invisible, non-staining preparation, which is cosmetically acceptable for treatment of face and scalp infections.

FUCYN-B Cream is indicated for the treatment of eczematous dermatoses including atopic eczema, infantile eczema, discoid eczema, stasis eczema, contact eczema, lichen simplex chronicus, psoriasis, discoid lupus erythematosus and seborrhoeic eczema when secondary bacterial infection is confirmed or suspected.

FUCYN-H Cream is indicated for the treatment of dermatitis, including atopic dermatitis and contact dermatitis, where an infection with bacteria sensitive to fusidic acid is suspected or confirmed. Because of its hydrocortisone content, Fucyn-H cream is particularly appropriate in cases where a milder corticosteroid is indicated, including milder inflammatory dermatoses - on the face and on children's skin. Fucyn-H cream is cosmetically acceptable for use on the face and hands and convenient for use in the groin area and armpits.

DOSAGE & ADMINISTRATION:**FUCYN Cream 2% w/w****Adults and Pediatric population:**

Uncovered lesions - apply gently three or four times daily.

Covered lesions - less frequent applications may be adequate.

FUCYN-B Cream

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 Fucyn-B cream can be enhanced by occlusion with polythene film. Overnight occlusion is usually adequate.

FUCYN-H Cream**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.

PHARMACOKINETICS:

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.

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.

PRECAUTIONS

Bacterial resistance among *staphylococcus aureus* has been reported to occur with the use of topical fusidic acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance. Extended or recurrent use may increase the risk of developing contact sensitisation.

Fusidic acid cream should therefore be used with care when applied in the proximity of the eyes. 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 topical therapy with Fusidic acid/ betamethasone, Fusidic acid/ hydrocortisone should be avoided. Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fusidic acid/ betamethasone, Fusidic acid/ hydrocortisone

Due to the content of corticosteroid, Fusidic acid/ betamethasone, Fusidic acid/ hydrocortisone should be used with care near the eyes. 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. Fusidic acid/ betamethasone, Fusidic acid/ hydrocortisone should be used with care in children as pediatric 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.

Due to the content of betamethasone valerate, prolonged topical use of Fusidic acid/ betamethasone 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 steroid 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 content of corticosteroid having immunosuppressant effect, Fusidic acid/ betamethasone, Fusidic acid/ hydrocortisone 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.

Due to the content of 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.

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 fetoneonatal toxicity of corticosteroids.

However, based on a general knowledge about systemic corticosteroids, caution should be exercised when using Fucyn-H cream during pregnancy.

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. Fucyn-B should not be used during pregnancy unless clearly necessary.

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.

SIDE EFFECTS:

The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by application site conditions such as pain and irritation, which all occurred in less than 1% of patients. Systemic undesirable class effects of corticosteroids like betamethasone valerate/ hydrocortisone include adrenal suppression especially during prolonged topical administration. Raised intra-ocular pressure, glaucoma or 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. 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.

CONTRAINDICATIONS:

Hypersensitivity to the active substance or to any of the excipients. Due to the content of corticosteroid, Fusidic acid / betamethasone, Fusidic acid / hydrocortisone 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.
- Skin manifestations in relation to tuberculosis or syphilis, either untreated or uncontrolled by appropriate therapy.
- Perioral dermatitis and rosacea.

STORAGE & INSTRUCTIONS:

Storage temperature for FUCYN Cream, FUCYN-B Cream & FUCYN-H Cream is 15-30°C. Protect from heat, sunlight and moisture. Do not freeze or refrigerate. Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

FOR EXTERNAL USE ONLY.

HOW SUPPLIED:

FUCYN Cream 2% w/w: 15g

FUCYN-B Cream: 15g

FUCYN-H Cream: 15g

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

فیوس کریم، فیوس۔ بی کریم اور فیوس۔ ایچ کریم کو ۱۵-۳۰ ڈگری سینٹی گریڈ

درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی اور نمند ہونے سے بچائیں۔

ریفریجریٹر میں نہ رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے

نسخے پر فروخت کریں۔ صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.