

ZUDIC-HC Cream

(Fusidic Acid BP + Hydrocortisone Acetate BP)

ذیوڈک - ایچ سی کریم
(فیوسیدک ایسڈ + ہائیڈروکورتیسون ایسیٹیت)

COMPOSITION: Each gram contains:

Fusidic Acid BP 20mg.

Hydrocortisone Acetate BP ... 10mg. [Innovator's Specs.]

INDICATIONS: ZUDIC-HC 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.

PHARMACODYNAMICS: ZUDIC-HC Cream combines the potent topical antibacterial action of Fusidic Acid with the anti-inflammatory and antipruritic effects of Hydrocortisone Acetate. 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.

PHARMACOKINETICS: There are no data which define the pharmacokinetics of ZUDIC-HC Cream, following topical administration in man. 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 Acetate is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Absorbed Hydrocortisone Acetate is extensively metabolised and rapidly eliminated in the urine.

DOSAGE AND ADMINISTRATION:

Adults and Paediatric Population:

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.

CONTRA-INDICATIONS: Hypersensitivity to Fusidic Acid/sodium fusidate, Hydrocortisone Acetate or to any of the excipients. Due to the content of corticosteroid, ZUDIC-HC Cream is contraindicated in the following conditions:

1. Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment.
2. Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy.
3. Perioral dermatitis and rosacea.

ADVERSE REACTIONS:

Immune system disorders	Rare: Hypersensitivity
Eye disorders	Not Known: Vision blurred
Skin and subcutaneous tissue disorders	Uncommon: Dermatitis contact, Eczema (condition aggravated) and rash
General disorders and administration site conditions	Common: Application site reaction (incl. pruritus, burning and irritation).

WARNINGS AND PRECAUTIONS: - Long-term continuous topical therapy with ZUDIC-HC Cream should be avoided. - Depending on the application site, possible systemic absorption of Hydrocortisone Acetate should always be considered during treatment with ZUDIC-HC Cream.

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- Due to the content of corticosteroid, **ZUDIC-HC Cream** 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 with or without occlusions following systemic absorption of topical corticosteroids.

- **ZUDIC-HC 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.

- 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.

- 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, **ZUDIC-HC 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.

- As **Zudic-HC 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.

OVERDOSAGE: 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 **ZUDIC-HC Cream** does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

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 fetoneonatal toxicity of corticosteroids. **Zudic-HC Cream** can be used during pregnancy if clinically needed. However, based on a general knowledge about systemic corticosteroids, caution should be exercised when using **Zudic-HC Cream** during pregnancy.

Breastfeeding: **Zudic-HC Cream** can be used during breastfeeding but it is recommended to avoid applying **Zudic-HC Cream** on the breast.

Fertility: There are no clinical studies with **Zudic-HC Cream** regarding fertility.

INTERACTION: No interaction studies have been performed. Interactions with systemically administered medicinal products are considered minimal.

INSTRUCTIONS: Store below 30°C. Protect from heat and light. Keep out of the reach of children. **FOR EXTERNAL USE ONLY.**

PRESENTATION: **ZUDIC-HC Cream** is available in tube of 5g and 15g.



Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی اور روشنی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔ صرف بیرونی استعمال کے لئے۔

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