

Fusiderm[®] B Cream

Fusidic acid & Betamethasone valerate

COMPOSITION:

Each gram contains 20mg Fusidic acid and 1mg betamethasone (as valerate), in a cream soluble base.

THERAPEUTIC INDICATIONS:

Fusiderm B cream is indicated for the treatment of eczematous dermatoses including atopic eczema, infantile eczema, discoid eczema, stasis eczema, contact eczema and seborrhoeic eczema when secondary bacterial infection is confirmed or suspected.

DOSAGE AND ADMINISTRATION:

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 Fusiderm B cream can be enhanced by occlusion with polythene film.

CONTRAINDICATIONS:

Acne rosacea and perioral dermatitis. Skin lesions of viral or fungal origin. Hypersensitivity to the preparation.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Long-term continuous topical steroid therapy should be avoided, particularly in infants and children. Adrenal suppression can occur even without occlusion. Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with potent topical steroids. Caution should be exercised if Fusiderm B cream is used near the eye. Glaucoma might result if the preparation enters the eye. Systemic chemotherapy is required if bacterial infection persists.

Bacterial resistance has been reported to occur with the use of fusidic acid applied topically. As with all topical antibiotics, extended or recurrent application may increase the risk of contact sensitization and the development of antibiotic resistance.

Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions.

PREGNANCY AND LACTATION:

Topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

UNDESIRABLE EFFECTS:

Prolonged and intensive treatment with potent corticosteroids may cause local atrophic changes

in the skin, including striae, thinning and dilation of superficial blood vessels, particularly when applied to the flexures or when occlusion is employed. As with other topical corticosteroids sufficient systemic absorption to produce hypercorticism can occur with prolonged or extensive use. Infants and children are at particular risk, more so if occlusive dressings are used. A napkin may act as an occlusive dressing in infants. Hypersensitivity reactions to fusidic acid are rare and Fusiderm B does not contain lanolin. However, if signs of hypersensitivity occur, treatment should be withdrawn.

PHARMACEUTICAL PARTICULARS:

List of excipients

Propylene Glycol, Chlorocresol, Liquid Paraffin, Cetostearyl Alcohol, White Soft Paraffin, Cetomacrogol, Sodium Dihydrogen Phosphate Anhydrous, Purified Water.

STORAGE :

Store below 30° C.

AVAILABILITY :

Fusiderm B cream is available in tubes.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Manufactured by **SPIMACO**
Al-Qassim Pharmaceutical Plant
Saudi Pharmaceutical Industries &
Medical Appliances Corporation,
Saudi Arabia

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