Axcel®

FUSIDIC ACID-B
CREAM (NEW FORMULA)

MAL

COMPOSITION:

Fusidic Acid (micronised)	2.0% w/w
Betamethasone as Valerate (micronised)	0.1%w/w

Chlorocresol 0.1% w/w as preservative.

PRESENTATION:
A white, water-miscible cream.

INDICATIONS:
Inflammatory dermatoses where bacterial infection is present or likely to occur, ie. atopic eczema, discoid eczema, stasis eczema, seborrhoiec dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

PHARMACOLOGY:
Fusidic acid penetrates normal or inflamed skin and achieves bactericidal concentrations down to the lower corium. Betamethasone valerate is well absorbed from sites of local application. When administered by topical application, particularly to large areas, when the skin is broken, or under occlusive dressing, sufficient corticosteroid may be absorbed to give systemic effects.

DIRECTION FOR USE:
For external use only.
Uncovered lesions : 2-3 daily applications.
Covered lesions : Less frequent application may be adequate.

CONTRAINDICATIONS:
Viral skin diseases, bacterial infection, perioral dermatitis, acne rosacea, fungal skin infection, ulcerative conditions & hypersensitivity to the preparation. Application to eye.

PRECAUTIONS:
When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic toxicity. They should be treated symptomatically, where possible the dosage being reduced or the drug slowly withdrawn. Repeated topical use of the cream may lead to problems of resistance and prolonged use on flexures and intertriginous areas should be avoided. Not to be used in the eye as there is a potential risk of glaucoma.

Use in Pregnancy & Lactation:
The safety of usage during pregnancy has not been fully established. Therefore, it should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time.

Use in Children & Infant:
Avoid prolonged use in infants. Babies and children up to 4 years should not be treated with dermal steroid for more than 3 weeks. Avoid the use on face.

SIDE EFFECTS:
Hypersensitivity has rarely been encountered. It should be avoided in patients known to be hypersensitive to fusidate. Excessive application to the skin has led to loss of skin collagen and subcutaneous atrophy, eg. striae, thinning and dilation of the superficial blood vessels especially when skin folds are involved.

DRUG INTERACTION:
No known drug interaction to date.

OVERDOSAGE:
Prolonged use of topical corticosteroids to large or extensive areas, especially with occlusive dressing, may lead to systemic side effects, which result from excessive action on electrolyte balance, excessive action on other aspects of metabolism including gluconeogenesis, the action on tissue repair and healing, and an inhibitory effect on the secretion of corticotropin by the anterior lobe of the pituitary gland. Disturbance of electrolyte balance is manifest in the retention of sodium and water, with oedema and hypertension, and in the increases excretion of potassium with the possibility of hypokalemic alkalosis. Other excessive metabolic effects lead to mobilisation of calcium and phosphorus, with osteoporosis and spontaneous fractures, nitrogen depletion, and hyperglycaemia with precipitation of the diabetic state. Patients may be more susceptible to infections including tuberculosis and viral infections. Large doses of corticosteroids may also produce Cushingoid symptoms, a typical hyperactivity of the adrenal cortex, with moon-face, sometimes with hirsutism, buffalo hump, flushing, increased bruising, striae, and acne, and sometimes leading to a fully developed Cushing's syndrome. If administration is discontinued these symptoms are usually reversed, but sudden cessation is dangerous.

OVERDOSAGE AND TREATMENT:
Treatment of overdosage are symptomatic, with the drug slowly withdrawn.

STORAGE:
Keep container well closed. Store below 30^{o}C.
Protect from light.

KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

PACK QUANTITIES:
Available in aluminium tube of 5g and 15g.

Further information can be obtained from pharmacist, physician or the manufacturer.

Product Registration Holder & Manufacturer :
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