Flupro®

Fluticasone Propionate

COMPOSITION:

Flupro ® 0.05% Cream: Each 100 mg of Flupro Cream contains 0.05 mg Fluticasone propionate BP.

PHARMACOLOGY:

Fluticasone propionate is a glucocorticoid with high topical anti-inflammatory potency, but a low HPA-axis suppressive activity after dermal administration. It, therefore, has a therapeutic index which is greater than most of the commonly available steroids. Fluticasone propionate has a high degree of selectivity for the glucocorticoid receptor, in vitro studies show that Fluticasone propionate has a strong affinity for the agonist activity at human glucocorticoid receptors. This receptor is believed to be responsible for the anti-inflammatory properties of glucocorticoids. Fluticasone propionate has weak affinity for the progesterone receptor and virtually no affinity for the mineralocorticoid, estrogen or androgen receptors. The therapeutic potency of glucocorticoids is related to the half-life of the glucocorticoid-receptor complex. The half-life of the Fluticasone propionate glucocorticoid-receptor complex is approximately 10 hours.

INDICATION:

Flupro ® Cream is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive eczema/dermatitis.

DOSE & ADMINISTRATION:

Apply a thin layer of Flupro ® cream to the affected skin areas once daily.

CONTRA-INDICATIONS:

Fluticasone propionate is contraindicated in Rosacea, Acne vulgaris, Peri-oral dermatitis, Primary cutaneous viral infections (e.g., Herpes simplex, chicken pox), Hypersensitivity to any of the ingredients, Perianal and genital pruritus etc. The use of Fluticasone propionate is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi or bacteria and dermatoses in children under three month of age, including dermatitis and napkin eruptions.

WARNING AND PRECAUTION:

Fluticasone propionate has a very low propensity for systemic absorption, nevertheless prolonged application of high doses to large areas of body surface, especially in infants and small children might lead to adrenal suppression. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. The face, more than other areas of the body may exhibit atropic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating severe eczema. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressing and so the skin should be cleansed before a fresh dressing is applied. Topical corticosteroids can produce reversible HPA axis suppression with the potential for clinical glucocorticoid insufficiency. Predispose to HPA axis suppression include large treatment surface areas, prolonged use, use under occlusion, altered skin barrier, liver failure, and young age Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids. If HPA axis suppression is suspected, gradually withdraw the cream, reduce the frequency of application, or substitute with a less potent corticosteroid. An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression. Pediatric patients may be at greater risk of HPA axis suppression due to their higher skin surface area to body mass ratios.

SIDE EFFECTS:

Fluticasone propionate preparations are usually well tolerated; local burning and pruritus have been reported. If signs of hypersensitivity appear, application should be stopped immediately. Prolonged and intensive treatment with potent corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae, dilation of the superficial blood vessels, hypertrichosis and hypopigmentation. Secondary infection, particularly when occlusive dressings are used or when skin folds are involved and allergic contact dermatitis have also been reported with corticosteroid use. Exacerbation of the signs and symptoms of the dermatoses have been reported with corticosteroid use. Prolonged use of large amounts of corticosteroids or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercorticism. This effect is more likely to occur in infants and children if occlusive dressings are used. In infants the napkin may act as an occlusive dressing.

USE IN PREGNANCY & LACTATION:

Administration of Fluticasone propionate during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. The excretion of Fluticasone propionate into human breast milk has not been investigated. Plasma levels in patients following dermal application of fluticasone propionate at recommended doses are likely to be low. When Fluticasone propionate is used in breast feeding mothers, the therapeutic benefits must be weighed against the potential hazards to mother and baby.

USE IN CHILDREN & ADOLESCENTS:

For adolescents and children aged > 3 month of age and over, apply a thin film of Flupro ® cream to the affected skin areas once daily with caution or as diracted by the physician.

DRUG INTERACTION:

No information is available.

OVERDOSE:

Acute overdosage is very unlikely to occur. However in case of chronic overdosage or misuse the features of hypercorticism may appear and in this situation as with any corticosteroid application should be discontinued. Overdosage by ingestion of Fluticasone propionate cream or ointment is extremely unlikely to occur due to the very low oral bioavailability of Fluticasone propionate

STORAGE:

Store in a dry and cool place below 30^0 C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Flupro ® 0.05% Cream: Each box contains an Aluminium tube of 10 gm cream.

Manufactured by
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