210mm

140mm

Cream / Lotion

Protica

(Fluticasone propionate)

پروٹیکا کریم/لوشن

(فلوٹیکاسون پروپاؤنیٹ)

COMPOSITION

Protica Cream

Each gram contains:

Fluticasone propionate……..……0.5mg

(USP specifications)

Protica Lotion 0.05% w/w

Each gram contains:

Fluticasone propionate.....……0.5mg (0.05%)

(USP specifications)

DESCRIPTION

Protica cream and lotion contains fluticasone propionate, a synthetic fluorinated corticosteroid, for topical dermatologic use. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

MECHANISM OF ACTION

Fluticasone propionate as a glucocorticoid has anti-inflammatory and vasoconstrictive features. Applied topically on the skin it suppresses inflammatory reactions and symptoms although without curing the underlying disorder. Systemic absorption through the subcutaneous tissues is low.

INDICATIONS

Protica Cream:

For adults and children aged 1 year and over:

Fluticasone propionate is indicated for symptomatic treatment of inflammatory dermatoses not caused by micro-organisms and responsive to corticosteroids such as:

- Eczema including atopic and discoid eczemas
- Psoriasis (excluding widespread plaque psoriasis)
- Lichen planus
- Lichen
- Contact sensitivity reactions
- Discoid lupus erythematosus
- As adjunct to systemic steroid therapy in generalized erythroderma

Children

For children aged 1 year and over who are unresponsive to lower potency corticosteroids, this medicine is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis under the supervision of a specialist. Expert opinion should be sought prior to the use of this medicine in other corticosteroid responsive dermatoses in children.

Protica Lotion:

Protica lotion is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis in patients 1 year of age or older. The safety and efficacy of drug use for longer than 4 weeks in this population have not been established. The safety and efficacy in pediatric patients below 1 year of age have not been established.

DOSAGE & ADMINISTRATION

Protica Cream:

For topical administration.

For adults and children aged 1 year and over:

Apply a thin film of fluticasone cream to the affected skin areas one to twice daily.

Duration of use:

Daily treatment should be continued until adequate control of the condition is achieved.

Frequency of application should thereafter be reduced to the lowest effective dose.

When fluticasone cream is used in the treatment of children, if there is no improvement within 7-14 days, treatment should be withdrawn and the child re-evaluated. Once the condition has been controlled (usually within 7-14 days) frequency of application should be reduced to the lowest effective dose for the shortest possible time. Continuous daily treatment for longer than 4 weeks is not recommended.

An increase in the number of daily applications might aggravate side effects without improving the therapeutic effects.

Method of administration:

In adults and children, use the method of finger-tip unit to specify the quantity of cream applied to a given surface. The finger-tip unit corresponds to the amount of cream applied from the distal skin-crease to the tip of the index finger. This quantity permits to treat a skin surface corresponding to 2 hands of an adult (approximately 250 to 300 cm2). A finger-tip unit corresponds to approx. 0.5g of product. A tube of 15 grams contains 30 finger-tip unities.

Protica Lotion:

Protica Lotion may be used in adult and pediatric patients 1 year of age or older. The safety and efficacy in pediatric patients below 1 year of age have not been established.

Atopic Dermatitis: Apply a thin film of Lotion to the affected skin areas once or twice daily. Rub in gently.

Other corticosteroid responsive dermatoses:

Apply a thin film of lotion to the affected skin areas once daily. Rub in gently.

As with other corticosteroids, therapy should be discontinued when control is achieved.

If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. The safety and efficacy of drug use for longer than 4 weeks have not been established.

Protica Lotion should not be used with occlusive dressings or applied in the diaper area unless directed by a physician.

PHARMACOKINETICS

Pharmacokinetic data for the rat and the dog indicate rapid elimination and extensive metabolic clearance. Bioavailability is very low after topical or oral administration, due to limited absorption through the skin or from the gastrointestinal tract, and because of extensive first-pass metabolism. Distribution studies have shown that only minute traces of orally administered compound reach the systemic circulation, and that any systemically available radiolabel is rapidly eliminated in the bile and excreted in the faeces. Fluticasone propionate does not persist in any tissue, and does not bind to melanin. The major route of metabolism is hydrolysis of the S-fluoromethyl carbothioate group, to yield a carboxylic acid (Gr36264), which has very weak glucocorticoid or anti-inflammatory activity. In all test animal species, the route of excretion of radioactivity is independent of the route of administration of radiolabelled fluticasone propionate.

Excretion is predominantly faecal and is essentially complete within 48 hours. In man, too, metabolic clearance is extensive, and elimination is consequently rapid.

Thus, drug entering the system circulation via the skin will be rapidly inactivated. Oral bioavailability approaches zero, due to poor absorption and extensive first-pass metabolism. Therefore, systemic exposure to any ingestion of the topical formulation will be low.

PRECAUTIONS

- Prolonged application of high doses to large areas of body surface, especially in infants and small children, might lead to adrenal suppression. Children and infants have a greater surface area to body weight ratio compared with adults. Therefore, in comparison with adults, children and infants may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. 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. Care should be taken when using fluticasone cream to ensure the amount applied is the minimum that provides therapeutic benefit.
- The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.
- The prolonged use of corticosteroids on the face may cause steroid-induced dermatitis.
- These incidents disappear at withdrawal of treatment, but a sudden withdrawal may be followed by an acute adrenal insufficiency.
- Overt suppression of the HPA-axis (morning plasma cortisol less than 5 micrograms/dL) is very unlikely to result from therapeutic use of fluticasone propionate cream unless treating more than 50% of an adult's body surface and applying more than 20g per day.
- Long-term continuous use should be avoided in children. The safety and efficacy of fluticasone propionate when used continuously for more than 4 weeks has not been established.
- If signs of hypersensitivity appear, application should stop immediately.
- The safety and efficacy in pediatric patients below 1 year of age have not been established.
- If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye so as to avoid the risk of local irritation or glaucoma.
- 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.
- Topical steroids may be hazardous in psoriasis for a number of reasons, including rebound relapses, development of tolerances, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important and referral to a dermatologist is required before using Fluticasone to treat psoriasis in children.
- Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.
- 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.
- Contains cetostearyl alcohol, which may cause local skin reactions (e.g.: contact dermatitis).
- 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.

Pregnancy

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established; however, 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 foetus.

Lactation

The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the milk. However, plasma levels in patients following dermal application of fluticasone propionate at recommended doses are likely to be low.

SIDE EFFECTS

Infections and infestations

Secondary infections (particularly when occlusive dressings are used or when skin folds are involved) have been reported with corticosteroid use.

Immune system disorders

Hypersensitivity. If signs of hypersensitivity appear, application should stop immediately.

Endocrine disorders

Features of hypercortisolism

Prolonged use of large amounts of corticosteroids, or treatment of extensive areas, can result in sufficient systemic absorption to produce the features of hypercortisolism. This effect is more likely to occur in infants and children, and if occlusive dressings are used.

Vascular disorders

Dilation of superficial blood vessels

Prolonged and intensive treatment with potent corticosteroid preparations may cause dilation of the superficial blood vessels.

Eye disorders

Blurred vision.

Skin and subcutaneous tissue disorders

Pruritus, local burning, Thinning, striae, hypertrichosis, hypopigmentation, allergic contact dermatitis, exacerbation of dermatoses, pustular psoriasis. Vascular purpura, skin fragility, peri-oral dermatitis, rosacea, scab, leg ulcer, acne, impaired healing. Local burning and pruritus have been reported. Prolonged and intensive treatment with potent corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae, hypertrichosis and hypopigmentation. Exacerbation of the signs and symptoms of the dermatoses and allergic contact dermatitis have been reported with corticosteroid use. Treatment of psoriasis with a corticosteroid (or its withdrawal) may provoke the pustular form of the disease. Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules

CONTRAINDICATIONS

- Rosacea
- Acne vulgaris
- Perioral dermatitis
- Primary cutaneous viral infections (e.g.: herpes simplex, chickenpox)
- Hypersensitivity to the active substance or to any of the excipients.
- Perianal and genital pruritus
- Ulceration of the skin
- Atrophy of the skin
- Fragile skin vessels
- Ichthyosis
- Juvenile dermatosis
- Dermatoses in infants under 1 year of age, including dermatitis and napkin eruptions
- Injuries ulcerated
- The use of fluticasone cream / lotion is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria.

STORAGE & INSTRUCTIONS

Store between 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

Protica Cream

5g and 10g tube.

Protica Lotion 0.05% w/w

20ml in plastic bottle

خوراک و ہدایات:

متاثرہ حصے پر دن میں ایک سے دو بار لگائیں۔

دوا کو ۱۵-۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی نمی اور منجمد ہونے سے بچائیں۔ 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.

210mm

140mm