

TRITON PHARMA INC.**PRESCRIBING INFORMATION****Pr****Topiderm HC 2%**

Hydrocortisone acetate 2% Cream

CONTAINS :

Hydrocortisone acetate USP 2% w/w

Also contains:

Stearyl alcohol

Cetyl palmitate

Petrolatum

Stearic acid

Arlacel

Polysorbate

Glycerine

Carbopol

Sodium hydroxide

Purified water

*Glydant plus (preservative blend containing the germicide DMDM Hydrantoin and the fungicide Iodopropynyl Butylcarbamate)***INDICATIONS :**

Inflammatory dermatoses. Topical therapy of acute and chronic corticosteroid responsive dermatoses including psoriasis, eczematous dermatoses, lichen simplex chronicus, seborrheic dermatoses. Symptomatic relief of allergic or contact dermatitis.

CONTRAINDICATIONS:

Tuberculous and fungal skin infections, herpes simplex, vaccinia and varicella.
Hypersensitivity to any of the product's ingredients.

Topiderm HC 2%**PRECAUTIONS:**

Not for ophthalmic use. Use cautiously on areas around or close to the eyes.

Although hypersensitivity reactions have been rare with topically applied steroids, discontinue NEO-HC 2% cream and initiate appropriate care if signs of sensitivity occur.

In bacterial skin infections, use appropriate antibacterial agents as the primary therapy; with the topical steroid application as an adjunct to control inflammation, erythema and itching. If a symptomatic response is not noted within a few days to a week discontinue use of the cortico-steroid until the infection is controlled.

Significant systemic absorption may occur when steroids are applied over large areas of the body, especially under occlusive dressing. To minimize this possibility during long term therapy it is suggested to interrupt the treatment periodically or to treat one area of the body at a time.

Pregnancy: Safety and efficacy of this product has not been demonstrated during pregnancy. Use with caution.

ADVERSE EFFECTS:

When occlusive dressings are used, pustules, miliaria, folliculitis and pyoderma may occur. The following adverse skin reactions have been reported, though rarely, with the use of topical cortico-steroids. – dryness, itching, burning, local irritation, striae, hypo pigmentation, atrophy and secondary infection.

DOSAGE:

Apply gently to the affected area 2 to 3 times daily or as directed by the physician.

CAUTION:

Discontinue use in the presence of irritation or allergic response.

WARNING:

Not for ophthalmic use.