

P^f DERMAFLEX-HC 1% CREAM

DIN: 00681989

1% Hydrocortisone Acetate in aqueous emollient hydrating base containing 10% Urea

Contained in the base is:

Stearic acid

White petrolatum

Stearyl alcohol

Cetyl palmitate

Sorbitan monostearate

Polysorbate 60

Purified water

Glycerin

Carbomer 934

Sodium hydroxide

Glydant plus (*preservative*)

INDICATIONS: Topical therapy for corticosteroid responsive dermatosis where anti-inflammatory, anti-allergic and anti-pruritic activity is indicated.

CONTRAINDICATIONS: Not to be used in untreated bacterial, fungal, or tubercular infected skin lesions. Not to be used in the presence of certain viral diseases which include: herpes simplex, varicella or vaccinia. Not be used with hypersensitivity to Hydrocortisone acetate, Urea, or other excipient to these products. A complete list of the contents will be made available upon request to physicians and pharmacists.

WARNINGS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

The safety of the fetus or child from the use of corticosteroids during pregnancy or lactation is not established. The prescribing physician must assess the risk/benefit factor during pregnancy or lactation. The use of occlusive dressing may have the effect of increasing percutaneous absorption of corticosteroids. Adrenal suppression and other systemic effects may occur with application to extensive areas, prolonged use or combinations thereof. Thermal homeostasis may be impaired if large areas of body are covered. Discontinue occlusive techniques if body temperature rises. It is suggested that large affected areas of the body be treated in smaller segments and at varied times. It is important to note that these formulations contain urea in the base which augments the penetration of the cortisone.

PRECAUTIONS: Use with caution on lesions in proximity of the eye. Discontinue use immediately if hypersensitivity occurs. In the case of bacterial skin infections, treat the infection first. Secondary infections can occur with prolonged use, and it is recommended to periodically interrupt therapy. Use extreme caution when treating patients with stasis dermatitis or other skin diseases with related blood circulation disorders.

If no symptomatic response is observed within a few days to a week, stop use and re-evaluate the patient's condition.

ADVERSE EFFECTS: Skin reactions can occur as a result of using topical steroids. These include any of the following symptoms or combinations: dryness, itching, burning, local irritation, atrophy of the skin and the subcutaneous tissue, pigmentary changes, hypertrichosis varicose veins and secondary infections. Also adrenal suppression has been reported with corticosteroids and sub-capsular cataracts have been associated with corticosteroids.

Note that significant systemic absorption can arise from use over a large surface area.

DOSAGE: Apply to the affected area with frequency of 2 to 3 times per day or as prescribed by the physician.

AVAILABLE:

225g JAR

120g Tube

SOOTHING TOPICAL TREATMENT OF DRY, INFLAMMED OR ITCHY SKIN CONDITIONS, BY THE ACTION OF HYDROCORTISONE ACETATE IN A LOTION OR CREAM

SUITABLE FOR CHRONIC USE DUE TO MINIMAL INCIDENCE OF ADVERSE REACTIONS.

THE STRATUM CORNEUM IS REHYDRATED AND MOISTURE LOSS IS MINIMIZED DUE TO THE ATTRACTION AND RETENTION OF WATER BY THE PRESENCE OF 10% UREA.

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