PRESCRIBING INFORMATION

MEDROL* TOPICAL 0.25%

(methylprednisolone acetate USP cream)

0.25% Cream

Glucocorticoid

Pfizer Canada Inc.
17,300 Trans-Canada Highway
Kirkland, Quebec H9J 2 M5

Date of Preparation:
23 September 2003

Control No. 086840

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Indications

Noninfected dermatoses, including allergic dermatoses, puritus ani and vulvea, atopic and seborrheic dermatitis and contact dermatitis, induced by poison ivy, cosmetics, chemicals or drugs.

Contraindications

Tuberculosis of the skin, herpes simplex vaccinia, varicella and other cutaneous infections for which an effective agent is not available for simultaneous application. Do not use in the eye or in patients sensitive to any of the components.

Precautions

Although untoward effects associated with the use of topical corticosteroids are uncommon and not to be expected from ordinary use, sensitization, irritation and failure of therapeutic response have been noted in rare instances. Application to extensive areas, too frequent application, or application under occlusive dressings may result in systemic absorption with symptoms of adrenal suppression, localized atrophy and striae. If secondary bacterial infection exists or supervenes, concomitant antimicrobial therapy is indicated.

Convulsions have been reported with concurrent use of methylprednisolone and cyclosporine. Since concurrent use of these agents results in a mutal inhibition of metabolism, it is possible that convulsions and other adverse events associated with the individual use of either drug may be more apt to occur.

Pregnancy

The safety of the use of topical steroid preparations during pregnancy has not been fully established. Therefore, steroids should not be used unnecessarily during pregnancy or for prolonged periods of time.

Adverse Effects

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

Dosage

Careful cleansing of the affected skin should precede the application of a small amount of cream. Initially, application may be made 1 to 3 times a day. Frequency of application may be reduced after control has been achieved.

Supplied

Each g contains: methylprednisolone acetate 2.5 mg (0.25%) in Veriderm, a skin lipid base. Nonmedicinal ingredients: butyl hyrolytol, butyl hydroxyan, butylpareben, cetly palmiate, cetyl alcohol, cholestrol, corn oil, glycerin, lexemul ar, methylparaben, mineral oil, oleic acid, oleyl alcohol, perfume oil, polyoxyl 40 stearate, sorbitan monooleate, squalene, stearic acid, stearyl alcohol, tocopherol and water. Tubes of 25 and 50 g.