PRESCRIBING INFORMATION

NEO-MEDROL*

(Methylprednisolone Acetate-Neomycin Sulfate)

25 g Topical Cream

Glucocorticoid - Antibiotic

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

Date of Preparation:
October 17, 2003

Control No. 087360

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INDICATIONS

An adjunct in the treatment of contact, atopic and seborrheic dermatitis, pruritus ani and vulvae, and neurodermatitis when complicated by infection caused by organisms sensitive to neomycin.

CONTRAINDICATIONS

Tuberculosis of the skin, chickenpox, herpes simplex, vaccinia, superficial fungus or yeast infections. Not for use in the eye. Known hypersensitivity 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.

Articles in current medical literature indicate an increase in the incidence of patients allergic to neomycin. The possibility of such a reaction should be borne in mind.

Ototoxicity and nephrotoxicity have been reported following absorption of topically applied neomycin.

Convulsions have been reported with concurrent use of methylprednisolone and cyclosporine. Since concurrent administration of these agents results in a mutual 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 corticosteroid preparations during pregnancy has not been fully established. Therefore corticosteroids should not be used unnecessarily during pregnancy or for prolonged periods of time.

ADVERSE EFFECTS

Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions and hypopigmentation have been reported with topical corticosteroids.

With the use of occlusive dressings, the occurrence of miliaria, folliculitis, pyodermas, and localized atrophy is a possibility. Contact sensitivity to a particular dressing material or adhesive may occur occasionally. When corticosteroid preparations are used for long periods in intertriginous areas or under occlusive dressings, striae may occur.

DOSAGE

Apply a small amount after careful cleansing of the affected skin. Initially, application may be made 1 to 3 times daily. After control has been achieved, the frequency of application may be reduced.

SUPPLIED

Each g contains: methylprednisolone acetate 2.5 mg (0.25%), neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base), in a synthetic skin lipid base. Nonmedicinal ingredients: butydhydroxyan, butydhydrolytol, butylparaben, cetyl palmitate, cetyl alcohol, cholesterol, corn oil, glycerin, lexemul ar, methylparaben, mineral oil, oleic acid, oleyl alcohol, perfume oil, polyoxyl 40 stearate, sorbitan monooleate, squalene, stearic acid, stearyl alcohol and tocopherol. Tubes of 25 g.