

PRESCRIBING INFORMATION

NEO-MEDROL* ACNE LOTION

(Methylprednisolone Acetate, Neomycin Sulfate,
Aluminum Chlorhydroxide Complex and Colloidal Sulfur)

25 mL & 75 mL

Acne Therapy

Pfizer Canada Inc
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Kirkland, Quebec H9J 2M5

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INDICATIONS

For control of acne vulgaris in the adolescent and young adult. Also in some cases of acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

In tuberculosis of the skin, herpes simplex, vaccinia, varicella and in other cutaneous infections which do not respond to neomycin. Known hypersensitivity to any of the components.

PRECAUTIONS

Avoid contact with eyes. If signs of irritation or sensitivity develop, application should be discontinued. As with any antibiotic containing product, overgrowth by resistant organisms may occur, particularly monilia. If this occurs, discontinue treatment and institute appropriate measures. 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.

If extensive areas are treated or if the occlusion technique is used, the possibility exists of increased absorption of the corticosteroid and suitable precautions should be taken. The prolonged use of antibiotic-containing preparations may result in overgrowth of nonsusceptible organisms, particularly fungi. If new infections appear during treatment, appropriate therapy should be instituted.

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.

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

Pregnancy: Although topical steroids have not been reported to have an adverse effect on pregnancy, the safety of their use has not absolutely been established. Therefore, use with care during pregnancy.

Children: When topical corticosteroids are applied for a prolonged period of time, sufficient systemic absorption can suppress the hypothalamic-pituitary-adrenal axis. Growth suppression may also occur.

ADVERSE EFFECTS

The following local adverse reactions have been reported with topical corticosteroids, either with or without occlusive dressings: burning sensation, itching, irritation, dryness, folliculitis, secondary infection, skin atrophy, striae, hypertrichosis, acneiform, eruptions, allergic contact dermatitis, laceration of the skin and hypopigmentation.

DOSAGE

After careful cleansing of the affected skin to minimize the possibility of introducing infection, Neo-Medrol Acne Lotion should be applied sparingly to the affected areas once or twice a day initially. Care should be taken to avoid contact with the eyes. The frequency of application will vary from patient to patient, depending on their susceptibility to the drying effect of the lotion, and may have to be reduced to every other day in some patients.

SUPPLIED

Each mL contains: methylprednisolone acetate 2.5 mg, neomycin sulfate 2.5 mg, aluminum chlorhydroxide complex 100 mg and colloidal sulfur 50 mg. Nonmedicinal ingredients: butylparaben, cetyl palmitate, lexemul ar, methylcellulose, methylparaben, perfume oil, polyethylene glycol, polysorbate 80, polysorbate 85 and propylene glycol. Plastic squeeze bottles of 25 and 75 mL.