PRESCRIBING INFORMATION

NAME OF THE MEDICINAL PRODUCT

Neo-Medrol® Acne Lotion

QUALITATIVE AND QUANTITATIVE COMPOSITION

NEO-MEDROL Acne Lotion contains Aluminum Chlorhydroxide Complex Solution 200 mg/ml, Sulfidal (Sulfur) 50.0 mg/ml, Methylprednisolone Acetate 2.5 mg/ml, Neomycin Sulfate 2.5 mg/ml

Excipients with known effect:
butyl hydroxybenzoate 0.3% and methyl hydroxybenzoate 0.2%.

PHARMACEUTICAL FORM

Lotion

CLINICAL PARTICULARS

Therapeutic indications

NEO-MEDROL Acne Lotion is used for the treatment of acne.

CONTRAINDICATIONS

In tuberculosis of the skin, herpes simplex, vaccinia, varicella and in other cutaneous infections which do not respond to neomycin.
Hypersensitivity to the active substance or to any of the excipients listed in section "PHARMACEUTICAL PARTICULARS"

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any

suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://sideeffects.health.gov.il/

DOSAGE AND ADMINISTRATION

After careful cleansing of the affected skin to minimise the possibility of introducing infection, NEO-MEDROL Acne Lotion should be applied sparingly to the affected areas once or twice a day initially. Avoid contact with the eyes. The frequency of application is dependent upon patients' susceptibility to the drying effect of the lotion, and may have to be reduced to every other day in some patients..

PHARMACEUTICAL PARTICULARS

List of excipients Inactive ingredients: lexemul ar, polyethylene glycol, propylene glycol, cetyl palmitate, polysorbate 80, butylparaben, methylcellulose, methylparaben, perfume oil, polysorbate 85and purified water.

Shelf life

The expiry date of the product is indicated on the packaging materials.

Special precautions for storage

Store below 25°C
After first opening the preparation can be used for 30 days.

Nature and contents of container

Plastic squeeze bottles of 25 and 75 mL

Not all pack sizes may be marketed.

MANUFACTURER

Patheon Inc., Whitby, Canada

LICENSE HOLDER

Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya

LICENSE NUMBER

113-49-22735

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