NEO-MEDROL®

Lotion

Methylprednisolone Acetate, Neomycin Sulphate, Aluminum Chlorohydrate, Sulfur

CDS

AfME Markets using same as LPD: Ghana, Kenya, Nigeria, Tanzania and Uganda

1. NAME OF THE MEDICINAL PRODUCT

NEO-MEDROL® ACNE LOTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NEO-MEDROL Acne Lotion: Each ml contains 2.5 mg methylprednisolone acetate, 2.5 mg neomycin sulfate (equivalent to 1.93 mg neomycin base), 200 mg aluminum chlorhydroxide (equivalent to 100 mg aluminum chlorhydroxide) and 50 mg sulfur

3. PHARMACEUTICAL FORM

Lotion

4. CLINICAL PARTICULARS

INDICATIONS

NEO-MEDROL Acne Lotion is indicated for the topical treatment of acne vulgaris, acne rosacea and seborrheic dermatitis. It is less useful in the treatment of cystic acne.

SAFETY

Contraindications

NEO-MEDROL Acne Lotion is contraindicated in patients with tuberculosis of the skin, herpes simplex, vaccinia, varicella, and in patients with a history of hypersensitivity to any component of the preparation.

Warnings & Precautions

Neomycin sulfate may occasionally induce sensitivity reactions. If signs of irritation or hypersensitivity develop, application should be discontinued.

If extensive areas are treated or if the occlusion technique is used, the possibility exists of increased absorption of the corticosteroid.

The prolonged use of antibiotic-containing preparations may result in overgrowth of non-susceptible organisms, particularly fungi.

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

Avoid contact with the eyes.

Events of epidural lipomatosis, central serous chorioretinopathy and pheochromocytoma crisis have been associated with systemic administration of corticosteroids. Long-term administration of inhaled or topical corticosteroid formulations may also be associated with these potential systemic effects.

Pediatric use - When topical corticosteroids are applied for a prolonged period of time, sufficient systemic absorption can suppress the hypothalamicpituitary- adrenal axis. Growth suppression may also occur.

Pregnancy and Lactation

Animal reproduction studies have not been conducted with neomycin sulfate-methylprednisolone acetate. It is also not known whether this combination can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Adverse Events

The following adverse reactions have been reported with topical corticosteroids: burning, itching, irritation, striae, skin atrophy, secondary infection, folliculitis, hypertrichosis, acneiform eruptions, hypersensitivity, allergic contact dermatitis, and hypopigmentation. NEO-MEDROL Acne Lotion is formulated to provide a drying action, therefore, dryness of the skin is associated with its use.

DOSING (POSOLOGY)

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. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Incompatibilities

There are no specific incompatibilities reported, however, it is generally not advisable to use more than one topical preparation at the same time.

5.2 Shelf life

Keep out of the sight and reach of children.
Do not use NEO-MEDROL after the expiry date which is stated on the Carton / Bottle label after EXP:. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

5.3 Special precautions for storage

Store below 30ºC

5.4 Nature and contents of container

NEO-MEDROL Acne Lotion is packaged in plastic squeeze bottles containing 25 ml.

5.5 Special precautions for disposal <and other handling>

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

FURTHER INFORMATION

MANUFACTURED BY

Patheon Inc
111 Consumers Drive,
Whitby, Ontario
Canada, L1N 5Z5

6. PRESCRIPTION STATUS

Prescription only medicine

DATE OF REVISION OF THE TEXT

May 2019