

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

**Neo-Medrol Acne Lotion®**

**Active ingredients**

Each ml contains:

methylprednisolone acetate 2.5 mg

neomycin sulphate 2.5 mg

sulfidal (sulfur) 50.0 mg

aluminum chlorhydroxide complex solution 200 mg

For a list of inactive ingredients and allergens in this preparation, see section 6 "Further information".

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**1. WHAT IS THIS MEDICINE INTENDED FOR?**

For treating acne.

**Therapeutic group:**

Methylprednisolone acetate – synthetic glucocorticoid.

Neomycin sulphate – antibiotic from the aminoglycoside group.

Sulfur – mineral (sulfur).

Aluminum chlorohydrate - mineral.

**2. BEFORE USING THIS MEDICINE**

**Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredients or any of the additional ingredients contained in the medicine (listed in section 6).
- you suffer from herpes simplex, cowpox, chicken pox, tuberculosis of the skin or any other skin infection which does not respond to neomycin.

**Do not use the medicine without consulting a doctor before starting treatment:**

- If you are pregnant.

**Special warnings regarding use of the medicine**

- If sensitivity or irritation develop, stop using the preparation.
- Do not use the preparation on broad skin areas, unless recommended by the attending doctor.
- If previously non-existent local inflammation develops during use of the preparation, stop using the preparation.
- Do not allow the preparation to come into contact with the eyes or ears. In the event of contact, wash immediately with water.
- Special caution is required when using in children and adolescents; use at these ages must be accompanied by medical supervision.

**Children and adolescents**

Prolonged topical use of preparations containing steroids may cause developmental delay.

**If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- Cyclosporine (to prevent rejection of transplants) since the combination of medicines may cause occurrence of seizures.

## **Pregnancy**

If you are pregnant, consult the doctor before starting treatment with the preparation.

## **3. HOW TO USE THIS MEDICINE?**

Always use this preparation according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

Unless instructed otherwise by the doctor, the recommended dosage is to apply once to twice a day.

Clean the skin well before applying the preparation.

### **Do not exceed the recommended dose.**

Do not swallow! This preparation is intended **for external use only**.

Avoid contact of the preparation with eyes and ears.

Shake the bottle well before use in order to form a uniform dispersion of the lotion.

**If you have taken an overdose, or if a child has accidentally swallowed some medicine**, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## **4. SIDE EFFECTS**

As with any medicine, use of Neo-Medrol Acne Lotion® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

### **Stop using the medicine and contact your doctor immediately in case of:**

An allergic reaction, rash or local inflammation that did not exist before using this preparation (rare).

**Additional side effects:** burning sensation, itching, redness, local atrophy, striations on skin, secondary infection, irritation, folliculitis, excessive hair growth in different areas of the body, skin lightening, lacerations of the skin, contact dermatitis, acne-like lesions, ototoxicity, nephrotoxicity. Part of the action of the preparation is drying the skin; therefore, dryness of the skin may be possible at the treated area.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

## **5. HOW TO STORE THE MEDICINE?**

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25°C.
- After first opening, the preparation can be used within 30 days.

## **6. FURTHER INFORMATION**

**In addition to the active ingredients, this medicine also contains:**

Lexemul ar, polyethylene glycol, propylene glycol, cetyl palmitate, polysorbate 80, butylparaben, methylcellulose, methylparaben, perfume oil, polysorbate 85 and purified water.

**What the medicine looks like and contents of the pack:**

A light yellow solution.

The preparation is provided in packaged bottles containing 25 ml or 75 ml.

Not all pack sizes may be marketed.

**Registration holder and address:**

Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

**Manufacturer's name and address:** Patheon Inc., Whitby, ON Canada.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:  
113.49.22735

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