

PATIENT PACKAGE INSERT IN ACCORDANCE WITH

THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine requires a doctor's prescription

Reading this package insert carefully in its entirety
before using this medicine

The format of this leaflet was determined by the Ministry of Health
and its content was checked and approved by it in May 2010

POLYCUTAN Cream

Composition:

Clotrimazole	1%
Dexamethasone Acetate	0.044%
Neomycin Sulfate	0.645%

Inactive ingredients: Sorbitan monostearate, polysorbate 60, cetyl esters wax, ceteosteryl alcohol, 2-octyldodecanol, benzyl alcohol, purified water.

Concentration of preservative: benzyl alcohol 1%

Therapeutic group:

Clotrimazole - antifungal of imidazole type.

Neomycin - aminoglycoside antibiotic.

Dexamethasone - corticosteroid.

Therapeutic activity: Treatment of dermatitis also involving a bacterial and/or fungal infection.

When should the preparation not be used?

Do not use this preparation if you are sensitive to any of its ingredients.
Do not use this preparation in cases of tuberculosis or syphilitic processes in the area requiring treatment, nor in viral diseases such as herpes or chickenpox.

Do not use this preparation without consulting a doctor before starting treatment in the following cases:

If you are pregnant or breastfeeding. If you are breastfeeding and the doctor approved use of this preparation, do not apply the cream on the breast before breastfeeding. If you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g. asthma), the vascular system, the liver, the immune system, from diabetes, glaucoma or cataract (in prolonged use of the preparation).

Warnings: Avoid using the preparation on extensive skin areas, open wounds and/or for prolonged periods (more than 4 weeks).

Avoid contact between this preparation and the eyes. If such contact occurs, rinse thoroughly with water. Avoid contact between this preparation and the face, if there is dermatitis around the mouth, or if the patient suffers from rosacea. Special care should be taken when treating children and adolescents. Use should be under medical supervision. Do not use occlusive dressing unless otherwise directed by the doctor (nylon baby diapers are considered occlusive dressing). If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this preparation.

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, including non-prescription medicines and nutritional supplements, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.

Side effects: In addition to the desired effect of the preparation, adverse reactions may occur during the course of treatment with this

preparation, for example: skin redness and irritation, dryness of the skin, sensation of heat and tingling in the treated area. These side effects usually disappear within a short time following the period of adaptation to the preparation.

Side effects that require special attention: If the above side effects do not disappear or if there is an allergic reaction to the preparation (rare): stop treatment and refer to the doctor. In case of excessive irritation or if there is no improvement or if there is even worsening of your condition (rare): stop treatment and refer to the doctor immediately! In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Adverse reactions and drug interactions in children and infants: Parents must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child!

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

Dosage: Dosage is according to doctor's instructions only.

Unless otherwise prescribed by your doctor, apply a thin layer of the cream twice daily (morning and evening) on the affected area and massage into the skin. If there is no improvement within a few days or if there is worsening of your condition, refer to your doctor.

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

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor in order to prevent recurrence of the infections.

Even if there is an improvement in your health, do not discontinue treatment before the designated time without consulting your doctor.

Avoid poisoning! This preparation, and all other medicines, must be stored in a safe place out of the reach of children and infants, to avoid poisoning. If a child has accidentally swallowed the preparation, proceed immediately to a hospital emergency room and bring the package of the preparation with you. Do not induce vomiting unless explicitly instructed to do so by a doctor! This preparation has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this preparation to your relatives, neighbours or acquaintances. Do not take medicines in the dark! Check the label and the dose each time you use your preparation. Wear glasses if you need them.

Storage: Store them in a cool place, below 25°C. After first opening can be used for 6 months. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the preparation to you. Do not store different medications in the same package.

License number: 4852.23172

Manufacturer: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.