

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with
a doctor's prescription only

POLYCUTAN® Cream

Active ingredients and quantities per dosage unit:

Each tube contains:

Clotrimazole	1%
Neomycin sulfate	0.645%
Dexamethasone acetate	0.044%

Inactive and allergenic ingredients in the preparation – see section 6 of the leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine.

If you have further questions, refer to the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of dermatitis also involving a bacterial and/or fungal infection.

Therapeutic group

Clotrimazole – a topical imidazole antifungal
Neomycin sulfate – an aminoglycoside antibiotic

Dexamethasone acetate – a corticosteroid

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine, including cetostearyl alcohol.
- If you have a known sensitivity to any other medicines from the aminoglycoside group.
- If you are suffering from herpes simplex or chickenpox.
- As with any other medicines for external use containing neomycin, do not use this medicine for external ear inflammation if you have a perforated ear drum.
- Do not use on the scalp.

Special warnings regarding use of the medicine

• Before treatment with Polycutan, tell the doctor if:

- You are pregnant or breastfeeding
- You are suffering or have suffered in the past from an impaired immune system function
- You are suffering or have suffered in the past from diabetes
- You are suffering or have suffered in the past from kidney problems
- You are suffering or have suffered in the past from dizziness
- You are suffering or have suffered in the past from tinnitus, hearing problems or

- hearing loss
- Do not use the medicine for any purpose other than that for which it was prescribed.
- Do not use this medicine on extensive skin areas or open wounds unless explicitly instructed to do so by the doctor.
- Avoid contact of the medicine with your eyes or mucous membranes (such as mouth and nose). If case of contact, rinse thoroughly with water.
- As with other creams, Polycutan may reduce the effectiveness of contraceptives made from rubber, such as condoms or diaphragms. If you use this medicine in your vagina or on your penis, use alternative forms of contraception for at least 5 days after using this medicine.
- If there is no improvement in your condition within 4 weeks, refer to your doctor.

Children and adolescents

Special caution is needed when treating children and adolescents. Use at these ages must be under medical supervision.

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy, breastfeeding and fertility

Fertility

Clotrimazole

There is no data that indicates fertility problems caused by the use of this active ingredient.

Dexamethasone acetate and neomycin sulfate

There is no information about the effect of these active ingredients on fertility.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult with a doctor before beginning treatment.

Driving and operating machinery

Clotrimazole

This active ingredient has no effect on the ability to drive or operate machinery, or its effect is negligible.

Dexamethasone acetate and neomycin sulfate

There is no information about the effect of these active ingredients on the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

This medicine contains 10 mg/g benzyl alcohol, which could cause mild local irritation. This medicine also contains cetostearyl alcohol, which could cause local skin reactions (e.g., contact dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment for the medicine.

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

The usual dose is generally:

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 there is a worsening of your condition, refer to the doctor.

Do not exceed the recommended dose.

Method of administration

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

Avoid contact with your eyes or mucous membranes (such as mouth and nose) (see warnings in section 2).

If case of contact with your eyes or mouth, rinse thoroughly with water and refer to a doctor.

If you accidentally took a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your condition, do not stop treatment with the medicine without consulting the doctor.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Polycutan may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

As with any medicine, there may be patients who are hypersensitive (allergic) to this cream. If you are allergic, a reaction will develop shortly after use of the medicine.

Stop treatment and refer immediately to a doctor or proceed to your nearest hospital emergency room if an allergic reaction develops. Signs of an allergic reaction may include:

- Swallowing or breathing problems
- Swelling of the lips, face, throat, tongue or other parts of the body
- Weakness, dizziness or fainting
- Nausea
- Local irritation, rash or inflammation (which were not there prior to using the medicine)
- Shortness of breath or difficulty breathing, wheezing (rare)

Additional side effects that may occur Redness, swelling, dryness, sensation of local heat and tingling, failure to heal. These effects usually pass within a short time after adaptation period to the medicine. However, if these effects are persistent and/or troublesome, consult with the doctor. Recurrent treatment with the medicine for a long time may cause changes in hair growth

and skin color, appearance of stretch marks on the skin and prominent veins, worsening of infections. In these cases, **stop treatment and refer immediately to the doctor.**

After using the medicine, you may experience: itching, rash, blisters, burning sensation, discomfort, swelling, irritation, pins-and-needles sensation, redness or skin peeling.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

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://sideeffects.health.gov.il>

Additionally, you can report to Padagis via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store in a cool place, under 25°C.
- After first opening, the medicine may be used for 6 months.
- Caution! Inflammable material, keep away from fire!
Do not light a cigarette or expose to fire before the medicine has fully dried.

6. FURTHER INFORMATION

• In addition to the active ingredients, the medicine also contains: 2-octyldodecanol, cetostearyl alcohol, cetyl esters wax, sorbitan monostearate, polysorbate 60, benzyl alcohol, purified water.

• What the medicine looks like and contents of the package: An aluminum tube containing 15 or 30 grams of a white cream. Not all package sizes may be marketed.

Name of manufacturer and registration holder:

Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

This leaflet was revised in April 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 048-52-23172-00

Polycutan is a registered trademark of Padagis Israel Pharmaceuticals LTD.