

POLYUCUTAN®

Cream

Active ingredients and their quantities per dosage unit:

Each tube contains:

Clotrimazole 1% w/w
Neomycin sulfate 0.645% w/w
Dexamethasone acetate 0.044% w/w

Inactive and allergenic ingredients in the medicine – see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

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, to other medicines from the aminoglycoside group or to any of the additional ingredients contained in the medicine, listed in section 6 "Further information".
- If you are suffering from viral infections, such as cold sores, herpes or chickenpox.
- If you are suffering from skin blisters or sores caused by a bacterial infection such as impetigo, skin tuberculosis.
- As with all medicines for external use containing neomycin, do not use this medicine for external ear inflammation if the ear drum is perforated.
- Do not use to treat nail or scalp fungus.

Special warnings regarding use of the medicine

- Do not use this medicine on extensive skin areas or open wounds unless explicitly instructed to do so by the doctor.
- Do not allow contact of the medicine with the eyes or mucous membranes (such as mouth and nose). In case of contact, rinse immediately with water.
- Do not smoke or come close to an open fire source due to risk of severe burns. Fabric (clothes, linens, dressings and the like) that was in contact with this medicine can easily ignite and is a serious fire hazard. Washing clothes and linens may reduce the amount of the medicine that has accumulated but will not remove it entirely.
- As with other creams, Polycutan may reduce the effectiveness of contraceptives made from rubber, such as condom or diaphragm. If you use this medicine in the vagina or on the penis, use alternative forms of contraception for at least five days after using this medicine.
- **Before treatment with Polycutan, tell the doctor if:**
 - You are using the cream under an occlusive dressing, including a baby's diaper. Such dressings enable the active ingredient to be absorbed more easily, and may cause overdose.
 - You have kidney problems. The doctor may decide to change the amount and frequency of applied cream.
 - You are suffering, or have suffered in the past, from hearing problems, hearing loss, ringing in the ears, dizziness.

If your condition gets worse while using the medicine, consult the doctor who prescribed the medicine to you – you may be experiencing an allergic reaction or your condition may require a different treatment.

If shortly after discontinuation of treatment, within two weeks, your condition reverts to what it was before treatment, do not start using this medicine again before consulting with the doctor who prescribed the medicine to you, unless the doctor first instructed you to do so.

If after treatment your condition reverts to what it was before treatment, and the redness spreads beyond the originally treated area and you experience a burning feeling, refer to a doctor before starting treatment again.

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 have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

If the medicine is absorbed into the body in large amounts, the neomycin component can extend or increase the effect of muscle relaxants during surgery.

If you are undergoing surgery, tell the doctor that you are using Polycutan.

Pregnancy, breastfeeding and fertility

Fertility

Clotrimazole

There are no data that indicate 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

Use of this medicine during pregnancy or breastfeeding is not recommended.

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult a doctor or pharmacist before using the medicine.

Driving and operating machinery

There is no effect on the ability to drive or operate machinery, or the effect is negligible.

Important information about some of the ingredients of the medicine

This medicine contains 10 mg benzyl alcohol per 1 gram of medicine, which could cause mild local irritation. This medicine also contains cetostearyl alcohol, which may 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 treatment regimen for the medicine.

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

The usual dosage 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 or there is even worsening of the condition within a few days, refer to the doctor.

Do not use the medicine to treat infants and children under 4 years of age for more than 3 weeks, especially in areas covered by a diaper.

If not indicated by the doctor, avoid occlusive dressings on the affected area (plastic diapers are occlusive dressings).

Use this medicine at set intervals, as determined by the attending doctor.

Do not exceed the recommended dose.

Method of administration

Do not swallow! This medicine is intended for **external use only**. If you accidentally swallowed the medicine, refer to a doctor immediately or proceed to the closest hospital emergency room.

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

In case of contact with the 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 forgot to take the medicine

If you forgot to take this medicine at the scheduled 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 health, 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 by 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.
- Rash.

Stop the treatment and refer to a doctor immediately if one of the following side effects occurs

- The condition of the skin worsens or the skin swells during treatment. You may be allergic to the medicine, have an infection or need a different treatment.

Additional side effects you may experience while using the medicine

- Irritation or itching in the area where the medicine is applied.
- Increased hair growth and change in skin colour.

Additional side effects that may occur

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

Side effects after prolonged use of Polycutan, use of a large amount each time, use under an occlusive dressing or diaper

- Thinning of the skin, skin that may be more easily damaged.
- Weight gain, rounding of the face and high blood pressure.

These effects can occur more frequently in infants and children.

Steroid withdrawal symptoms

After long-term continuous use, withdrawal symptoms may occur following discontinuation of use, including: redness of the skin which may extend beyond the area initially treated, burning or tingling sensation, intense itching, skin peeling, oozing sores.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the 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, they can be reported 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.
- Can be used for 6 months after first opening.
- 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.

Manufacturer and registration holder: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

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

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