

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

The medicine is dispensed with a doctor's prescription only

**Dermacombin Cream
Dermacombin Ointment**

Active ingredients

Each gram contains:

neomycin (as sulfate) 2.50 mg
triamcinolone acetonide 1.00 mg
gramicidin 0.25 mg
nystatin 100,000 IU

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start 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 the relief of corticosteroid-responsive inflammatory or pruritic dermatoses accompanied by infection due to bacteria and/or candida.

Therapeutic group:

Neomycin is an aminoglycoside antibiotic.

Triamcinolone is a corticosteroid.

Gramicidin is a polypeptide antibiotic.

Nystatin is an antifungal.

2. Before using the medicine:

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredients (neomycin, triamcinolone, gramicidin or nystatin) or to any of the other ingredients in this medicine (see section 6).
- If you have primary skin infections.
- If you have tuberculosis.
- If you have any serious skin lesions, most types of viral lesions of the skin (including chickenpox (varicella), cold sores or genital herpes (herpes simplex)), and fungal skin lesions except caused by yeast infections.
- In your eyes.
- In the outer area of your ear if you have an ear infection or holes in your eardrums (see section 4).
- Under covered skin dressing if you have skin swelling and infections.

Special warnings about using this medicine

Before or when using Dermacombin, tell your doctor if:

- You have used corticosteroids in the past.
- Your condition has not changed within 7 days.

- You use the medicine on large skin areas.
- You have skin lesions close to the eye.
- You have allergic reactions such as burning, itching, irritation, dryness, and skin discoloration.
- You have inflammation of the skin associated with impaired circulation (stasis dermatitis) or other skin diseases associated with impaired circulation.

Additional warnings:

Avoid contact of the preparation with the eyes. In case of such contact, rinse the eyes thoroughly with water.

If further skin irritation develops or the infection worsens, contact your doctor.

Avoid continuous or prolonged use of large quantities as the risk of side effects increases with longer use. Prolonged use may lead to development of steroid withdrawal syndrome when treatment is discontinued.

Children and adolescents

Special caution is required in use in children and adolescents. Use in this age group must include medical follow-up.

Drug interactions

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

Pregnancy and breastfeeding

If you are pregnant or if you are breastfeeding, do not use this medicine before you consult your doctor.

Important information about some of this medicine's ingredients**Dermacombin Cream**

The medicine contains propylene glycol.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

Directions for use: apply a thin layer of the medicine to the affected skin and rub it in gently.

- For external use only.
- Avoid contact with the eyes and mucous membranes (e.g., mouth and nose).
- Do not apply to open wounds or burns to avoid absorption of the medicine into the blood.

If you have accidentally used a higher dose

The following symptoms may appear, especially when using on large areas of skin or for an extended period of time: delayed healing, mild reversible suppression of adrenal function, subcapsular cataracts, ecchymoses, ulceration, peptic ulceration, hypertension, aggravation of infections, hirsutism, acne, edema and muscle weakness, nephrotoxicity and ototoxicity.

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

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every 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

Like with all medicines, using Dermacombin 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 taking this medicine and consult your doctor as soon as possible if:

- You suffer from local irritation or sensitization. Symptoms may include burning, itching, irritation, dryness, redness (erythema), allergic inflammation of the outer ear. Hypersensitivity reactions are rare.
- You notice atrophy of the skin (wasting of the skin) and subcutaneous tissues, particularly on flexor surfaces and on the face.
- You notice overgrowth of nonsusceptible organisms, including fungi other than candida.

Additional side effects:

Folliculitis, hirsutism, acneiform eruptions, tinnitus, deafness, change in skin pigmentation, striae (particularly when used for long periods in intertriginous areas or under occlusive dressings), damage to collagen, telangiectasis, adrenal suppression particularly when used on large areas or for a prolonged period, posterior subcapsular cataract (observed in systemic use of steroids), delayed healing.

Hemolysis (breakdown of red blood cells). Rare.

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) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. 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.
- **Storage conditions:** Store in a cool place below 25°C.
- Use within 6 months after opening.

6. Additional information

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

Dermacombin Cream:

Purified water, petrolatum white, cetomacrogol emulsifying wax, paraffin liquid, sodium phosphate dibasic, propylene glycol, citric acid, ethyl alcohol 95%, perfume, methyl paraben, propyl paraben

Dermacombin Ointment:

Paraffin liquid, polyethylene oxidized wax

What the medicine looks like and contents of the pack:

Dermacombin Ointment: Smooth yellow oily ointment, supplied in 5- or 15-gram aluminum tubes.

Dermacombin Cream: Smooth, yellowish water-washable cream, supplied in 5- or 15-gram aluminum tubes.

Not all pack sizes may be marketed.

Manufacturer and registration holder: Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761.

Revised in March 2021 according to MOH guidelines.

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

Dermacombin Cream: 133 54 23775 00

Dermacombin Ointment: 015 28 24536 00