

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

The medicine is dispensed with a doctor's prescription only

## **Tevacutan Skin cream**

### **Composition**

Clotrimazole 1% w/w  
Dexamethasone acetate 0.044% w/w  
Neomycin sulfate 0.645% w/w  
For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass this medicine 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 treatment of fungal infection of the skin that involves inflammation and/or secondary infection.

#### **Therapeutic class**

Clotrimazole – imidazole antifungal for topical use  
Dexamethasone acetate – corticosteroid  
Neomycin sulfate – aminoglycoside antibiotic

### **2. BEFORE USING THE MEDICINE**

#### **Do not use the medicine if:**

- You are sensitive (allergic) to any of the active ingredients of the medicine, to other aminoglycoside medicines, to the ingredient cetostearyl alcohol or to benzyl alcohol (see below under "Important information about some of the ingredients of the medicine"), or to any of the other ingredients listed in section 6 – "Additional information".
- You suffer from viral infections such as cold sores, herpes or chickenpox.
- You suffer from blisters in the skin or sores caused by a bacterial infection such as impetigo, or tuberculosis of the skin.
- You have a perforated eardrum. As with all external medicines containing neomycin, do not use this medicine for external ear inflammation if the eardrum is perforated.
- Do not use for treatment of fingernail fungal infection or on the scalp.

#### **Special warnings regarding the use of the medicine**

- Do not use this medicine on extensive skin areas or open wounds, unless specifically instructed by the doctor.
- Do not use this medicine for prolonged periods (more than 4 weeks).
- Do not allow the medicine to come in contact with the eyes or with mucous membranes (such as in the mouth and nose). In case of contact wash immediately with water.
- Unless indicated by the doctor, occlusive dressing of the affected area should be avoided (diapers are considered an occlusive dressing).
- Do not smoke or go near an open fire source due to the risk of severe burns. Fabric (clothes, bed linen, dressings etc.) that has been in contact with this medicine can ignite more easily and constitutes a fire hazard. Washing clothes and bed linen can decrease the amount of medicine that has accumulated, but will not remove it completely.
- As with other creams, Tevacutan may decrease the effectiveness of contraceptives made of rubber, such as condoms or diaphragms. If the medicine is being used on the vagina or penis, alternative contraceptives should be used for at least five days after using the medicine.
- **Before treatment with Tevacutan, tell the doctor if:**

- You are using the cream under an occlusive dressing, including a baby diaper. These dressings enable the active ingredient to get absorbed through the skin more easily, and may cause an overdose.
- You have kidney problems. The doctor may decide to change the amount and frequency of applying the cream.

- You suffer or have suffered in the past from hearing problems, hearing loss, ringing in the ears, dizziness.

If your condition worsens while using the medicine, consult the doctor who prescribed you the medicine – you may be having an allergic reaction or your condition may require another treatment. If within two weeks of stopping the treatment you experience a recurrence of your pre-treatment condition, do not use the medicine again before consulting the doctor who prescribed you the medicine, unless the doctor has instructed you beforehand to do so. If after the treatment you experience a recurrence of your pre-treatment condition, and during the recurrence the redness extends beyond the initially treated area and you experience a burning sensation, refer to the doctor before repeating the treatment.

Contact your doctor if you experience blurred vision or other visual disturbances.

#### **Children and adolescents**

Special caution is required when used in children and adolescents. Use at these ages must be accompanied by medical supervision.

Infants and children should not be treated for more than two weeks without an explicit instruction from the doctor.

#### **Drug interactions**

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

If the medicine is absorbed into the body in large amounts, the ingredient neomycin can increase or prolong the effect of medicines that relax the muscles during surgery. If you undergo surgery, tell the doctor that you have used Tevacutan.

#### **Pregnancy, breastfeeding and fertility**

##### **Fertility**

**Clotrimazole**  
There are no data indicating fertility problems due to the use of this ingredient.

**Dexamethasone acetate and neomycin sulfate**

No information is available regarding the effect of these ingredients on fertility.

##### **Pregnancy and breastfeeding**

Using this medicine during pregnancy or breastfeeding is not recommended. If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult a doctor or pharmacist before using the medicine.

##### **Driving and operating machinery**

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

##### **Important information about some of the ingredients of the medicine**

This medicine contains cetostearyl alcohol, which may cause local skin reactions such as contact dermatitis.

This medicine contains 1 gram of benzyl alcohol in every 100 grams of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

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

The generally accepted dosage is: apply twice a day (morning and evening).

#### **Instructions for use**

Avoid contact of the medicine with the eyes and mucous membranes (such as in the mouth and nose).

In case of contact wash thoroughly with water.

Apply a thin layer of the cream on the affected area and massage into the skin.

**Do not exceed the dose recommended by the doctor.**

If within a few days there is no improvement in your condition or if it even worsens, contact the doctor again. This medicine should be used at set intervals as determined by the doctor. **This medicine is intended for external use only.**

**If a child swallowed this medicine by mistake, immediately go to the doctor or to a hospital emergency room and bring the package of the medicine with you.** Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

**How can you contribute to the success of the treatment?**

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

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

### **4. SIDE EFFECTS**

**As with any medicine, using Tevacutan may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience 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 using the medicine.

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

- Problems swallowing or breathing
- Swelling of the lips, face, throat, tongue or other parts of the body
- Weakness, dizziness or fainting
- Nausea
- Rash

**Stop the treatment and contact the doctor immediately if any of the following side effects occurs**

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

**Other side effects you may experience while using the medicine**

- Irritation or itching where the medicine is applied.
- Increased hair growth and skin discoloration.
- Blurred vision.

#### **Other side effects that may occur**

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

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

- Thinning of the skin, skin that may be damaged more easily.
- Weight gain, rounding of the face and high blood pressure.
- These effects may occur more in babies and children.

#### **Symptoms of steroid withdrawal**

After continuous use for long periods, withdrawal symptoms may appear upon discontinuation of use, including: redness of the skin which may extend beyond the initial treatment area, burning or tingling sensation, intense itching, peeling of the skin, 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 may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

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

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not discard medicines via wastewater or the trash. Ask your pharmacist how to destroy medicines no longer in use. These measures will help to protect the environment.
- **Store below 25°C.**
- The medicine may be used for up to 12 months after first opening the tube, but no later than the expiry date.

### **6. ADDITIONAL INFORMATION**

In addition to the active ingredients the medicine also contains:

Octyldodecanol, cetostearyl alcohol, cetyl esters wax, sorbitan monostearate, polysorbate 60, benzyl alcohol, purified water.

**What does the medicine look like and what are the contents of the package?**

Each package contains a tube containing 15 grams of white to beige cream.

**Name and address of license holder and manufacturer**

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

**Registration number of the medicine in the national drug registry of the Ministry of Health:** 115-99-29683

This leaflet was revised in December 2025.