

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

The medicine is dispensed with
a doctor's prescription only

Tevacutan®

Skin cream

Composition

Clotrimazole 1%
Dexamethasone acetate 0.044%
Neomycin sulfate 0.645%

For the list of inactive ingredients
in the preparation, see section 6 –
“Further information”.

Read this 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 the treatment of your ailment. 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 the treatment of a fungal
infection of the skin involving
inflammation and/or secondary
infection.

Therapeutic group:

Clotrimazole: imidazole antifungal
Dexamethasone: corticosteroid
Neomycin: aminoglycoside
antibiotic

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- if you are sensitive (allergic) to
any of the active ingredients
of the medicine, to cetostearyl
alcohol, benzyl alcohol or to the
other ingredients listed in section
6 – “Further information” in this
leaflet.
- if you are suffering from viral
infections (e.g., herpes or
chickenpox), from tuberculosis
of the skin, from syphilis (a
venereal disease).
- for treatment of external ear
inflammation if the eardrum is
perforated.

Special warnings regarding use of the medicine:

- If you are sensitive to any food
or medicine, inform the doctor
before using the medicine.
- Do not use this medicine for a
purpose other than for which it
has been prescribed.
- Do not use this medicine on
extensive areas of the skin,
on open wounds and/or for
prolonged periods (more than 4
weeks).
- Do not allow this medicine to
come into contact with the eyes
and mucous membranes. In case
of contact, rinse thoroughly with
water.
- Special caution is required when
using in children and adolescents.
Use at these ages requires
medical supervision.
- In case of dermatitis around the
mouth or if you have rosacea, do
not allow this preparation to come
into contact with the face.
- Unless indicated by the doctor,
avoid occlusive dressing in
the affected area (diapers are
considered occlusive dressing).
- In case of treatment with the
medicine in an area covered
with a diaper, do not close it too
tightly.

Before treatment with Tevacutan, tell the doctor if:

- You are pregnant or breastfeeding
- You are suffering, or have suffered
in the past, from impaired function
of the:
 - liver
 - immune system
 - respiratory system (e.g.,
asthma)
 - vascular system
- You are suffering, or have suffered
in the past, from:
 - glaucoma or cataract (with
prolonged use)
 - diabetes

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding,
do not use this medicine without
consulting the doctor before
starting treatment.

If the doctor approved use of
the medicine for a breastfeeding
woman, do not apply to the breast
before breastfeeding.

Treatment in children

Parents must inform the attending
doctor of all side effects as well as
any other medicine being given to
the child.

Do not carry on treating infants and
children for more than two weeks
without explicit instruction from the
doctor.

Important information about some of the ingredients of the medicine

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

This medicine contains 1 gram
benzyl alcohol in every 100 gram
cream. Benzyl alcohol may cause
allergic reactions and mild localized
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.

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

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

Instructions for use:

Avoid contact between the
medicine and the eyes and mucous
membranes (e.g., in the mouth and
nose).

In case of contact, rinse thoroughly
with water.

Apply a thin layer of 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, refer to the doctor
again.

Use this medicine at specified time
intervals as determined by the
attending doctor.

**This medicine is intended for
external use only.**

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

Even if there is an improvement in
your health, do not stop treatment
with this 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
each time you take a medicine.
Wear glasses if you need them.
If you have further questions
regarding use of the medicine,
consult a doctor or pharmacist.**

4. SIDE EFFECTS:

As with any medicine, use of
Tevacutan cream may cause side
effects.

Do not be alarmed by the list of side
effects. You may not suffer from any
of them.

Discontinue treatment and refer immediately to the doctor

- In the case of an allergic reaction,
in cases of excessive irritation,
localized rash or inflammation
that did not exist before use of
the medicine (rare), swelling of the
face, tongue or throat, difficulty
in breathing or swallowing,
dizziness, fainting, weakness,
nausea, or skin blisters.
- If your condition does not improve
or if it worsens (rare).

Additional side effects

Itching, rash, burning, discomfort,
swelling, irritation or redness or
peeling of the skin.

Hearing problems.

Kidney problems (e.g., pain when
passing urine or blood in the
urine).

Temporary loss of sense of smell
or taste.

**If a side effect occurs, if any of
the side effects worsen, or if you
are suffering from a side effect
not mentioned in the leaflet,
consult 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>

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 of children and/or infants in
order to avoid poisoning. Do not
induce vomiting without explicit
instruction from 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.
- Do not discard medicines in the
wastewater or waste bin. Ask
the pharmacist how to dispose
of medicines no longer in use.
These measures will help protect
the environment.
- **Store below 25°C.**
- The medicine can be used for up
to 12 months after first opening
the tube, but no later than the
expiry date.

6. FURTHER 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 the medicine looks like and
the contents of the package:**

Every package contains a tube
which contains 15 grams of white
to beige cream.

**Name of Manufacturer and
License Holder and its Address:**

Teva Israel Ltd.,
194 Dvora HaNevi'a St., Tel Aviv
6244020.

**Registration number of the
medicine in the National Drug
Registry of the Ministry of Health:**
115-99-29683

**The leaflet was revised in
March 2022 according to MOH
guidelines.**