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

The medicine is dispensed with a doctor's prescription only

Tevaderm®

Skin cream

Composition

Isoconazole nitrate 1% w/w
Diflucortolone valerate 0.1% w/w

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some 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 your treatment. 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?

Topical treatment of inflammatory conditions of the skin accompanied by a secondary fungal infection.

Therapeutic class

Isoconazole nitrate - an antifungal of the imidazole group.

Diflucortolone valerate - a corticosteroid.

2. Before using the medicine

Do not use the preparation if:

- You are sensitive (allergic) to isoconazole nitrate or to diflucortolone valerate, or to any of the other ingredients the medicine contains (listed in section 6).
- You have skin lesions associated with a tuberculosis or syphilis infection in the area to be treated.
- You have a viral infection, e.g. herpes, shingles or chickenpox (varicella, herpes zoster).
- You have a chronic skin inflammation of the face (rosacea), a skin inflammation around the mouth (perioral dermatitis) or a skin reaction following vaccination in the area to be treated.
- Do not use the medicine in the first trimester of pregnancy.

Special warnings regarding the use of the medicine

Consult a doctor before starting treatment with Tevaderm. When using Tevaderm, it is important to know the following:

- If you also have a bacterial infection of the skin, your doctor will prescribe you another medicine to treat this infection, in addition to Tevaderm.
- Do not allow Tevaderm to come into contact with the eyes when applying it to your face.
- Extensive application of glucocorticoid-containing topical medicines to large areas of the body or for prolonged periods of time increases the risk of side effects. This is particularly true in areas of the body under occlusion (e.g. diapers, occlusive dressings, etc.).
- There is a risk of developing an eye condition called glaucoma if you apply Tevaderm around the eyes, or if Tevaderm is used with occlusive dressings in large amounts over a long period of time.
- When used in the genital areas, the preparation may cause damage to latex products such as condoms or diaphragms, and may reduce their efficiency as contraceptives or protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist if you require more information.
- Regular hygienic measures are essential for successful treatment with Tevaderm. To avoid renewed infection, you should:
  - Change your personal linen (face cloth, underwear etc., preferably made of cotton) daily and boil them.
  - Dry the areas between the toes thoroughly after washing.
  - Change your socks and stockings daily.

If symptoms do not improve, consult the doctor again.

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

Drug-drug interactions

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor before using this medicine. Your doctor will carefully weigh the benefits against the risks of using Tevaderm. Glucocorticoids should not be applied during the first three months of pregnancy to avoid any risk to the development of the unborn baby.

If you are pregnant, you should particularly avoid applying Tevaderm under an occlusive dressing or on extensive areas of the body, or using the cream for a long period of time.

It is not known whether the active ingredients of Tevaderm pass into breast milk. A risk to the breastfed infant cannot be excluded.

If you are breastfeeding:

- Do not apply the preparation to the breasts.
- Avoid applying Tevaderm under an occlusive dressing or to extensive parts of the body.
- Avoid using Tevaderm for a long period of time.

There are no data showing that fertility is affected by the use of Tevaderm.

Driving and operating machinery

No effects on the ability to drive and operate machinery have been observed in patients using the medicine.

Important information about some of the ingredients of the medicine

Tevaderm 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 how to use the preparation.

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

Do not exceed the recommended dose or the recommended duration of treatment.

If there is no improvement in your condition within a few days or if your condition worsens, contact the doctor again.

Do not use the preparation for more than two weeks, and contact the doctor to prescribe a follow-up treatment as necessary.

Use in children

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

Unless indicated by the doctor, occlusive dressing of the infected area should be avoided (plastic diapers are considered an occlusive dressing).

Method of use

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

Contact with the eyes, mucous membranes (e.g. in the mouth and the nose) should be avoided. In case of contact with the eyes, wash them thoroughly with water.

Always wash your hands before and after application of Tevaderm.

Maintaining hygiene is essential for successful treatment with Tevaderm (see section 2 - "Special warnings regarding the use of the medicine").

If you accidentally took a higher dose than recommended or if a child accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you have forgotten to take Tevaderm

Do not apply a double dose to make up for a forgotten dose. When you remember, apply the next dose and continue with the treatment as prescribed. See your doctor or pharmacist if you are worried.

Follow the treatment as recommended by the doctor.

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

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

4. Side effects

As with any medicine, using Tevaderm 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.

The following side effects have been observed in clinical studies. They are listed according to their frequency:

Common side effects: may affect up to 1 in 10 users:

- Skin irritation or burning sensation at the application site.

Uncommon side effects: may affect up to 1 in 100 users:

- Redness (erythema) or dryness at the application site.
- Stretch marks (skin striae).

Side effects occurring at an unknown frequency:

- Itching (pruritus) or blisters at the application site.
- Blurred vision.

As with other glucocorticoid-containing medicines that are applied to the skin, the following local side effects may also occur when using Tevaderm (their frequency cannot be determined):

Skin atrophy (thinning of the skin), inflammation of hair follicles (folliculitis), increased body hair growth (hypertrichosis), expansion of small superficial blood vessels in the skin (telangiectasia), skin inflammation around the mouth (perioral dermatitis), skin discoloration, acne, allergic skin reactions to any of the ingredients of the medicine.

Since the ingredients of Tevaderm are absorbed by the body through the skin, further side effects may occur in other parts of the body (systemic effects).

Side effects cannot be excluded in infants whose mothers have been treated extensively or for a prolonged period of time during pregnancy or while breastfeeding. For example, the activity of the infant's adrenal glands may be reduced (reduced adrenocortical function), and so the infant's resistance to diseases may be lowered.

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 your doctor.

<u>Reporting side effects</u>

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), 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.

Store below 25°C.

The medicine may be used up to 12 months after first opening, but not after the expiry date.

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

White soft paraffin, mineral oil heavy, cetostearyl alcohol, polysorbate 60, sorbitan monostearate, edetate disodium, purified water.

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

Each pack contains one 15-gram tube with white to off-white homogeneous cream.

Name and address of the manufacturer and marketing authorization holder

Teva Israel Ltd., 124 Devora Hanevia st., Tel Aviv.

The leaflet was revised in August 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 122.85.30213.

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