

PATIENT INFORMATION LEAFLET

TERBİSİL® PLUS 1% + 0.1% Cream

for Topical Use

- **Drug Substance:** Each gram of cream contains 10 mg of Terbinafine Hydrochloride and 1 mg of Mometasone Furoate.
- **Excipients:** Isopropyl myristate, benzyl alcohol, sorbitan monostearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, hexylene glycol, sodium hydroxide, and deionized water.

- **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed specifically for you. Do not give it to others.*
- *When you visit a doctor or hospital, inform them that you are using this medicine.*
- *Follow the instructions exactly as described in this leaflet. Do not use a higher or lower dose than the one prescribed for you.*

This Package Leaflet contains:

1. *What is TERBİSİL® PLUS and what is it used for?*
2. *What should be considered before using TERBİSİL® PLUS?*
3. *How to use TERBİSİL® PLUS?*
4. *What are the possible side effects?*
5. *How to store TERBİSİL® PLUS?*

1. What is TERBİSİL® PLUS and what is it used for?

TERBİSİL® PLUS is available in 20g and 30g packages, in a lacquered aluminum tube. The cream has a shiny, white, and homogeneous appearance.

TERBİSİL® PLUS contains terbinafine hydrochloride, which is effective in treating superficial skin fungal infections, and mometasone furoate, a potent corticosteroid with anti-inflammatory and antipruritic properties, which helps relieve symptoms such as inflammation, itching, burning, and soreness commonly seen in inflammatory and allergic skin conditions.

TERBİSİL® PLUS is used for the treatment of fungal infections associated with conditions like eczema (e.g., on the hands, feet, groin, or between the toes).

2. BEFORE USING TERBISIL® PLUS, PLEASE CONSIDER THE FOLLOWING

DO NOT USE TERBISIL® PLUS in the following cases:

If you have:

- A hypersensitivity (allergy) to terbinafine hydrochloride, mometasone furoate, or any other ingredient in TERBISIL® PLUS,
- Inflammatory lesions around the mouth,
- Skin reactions following vaccination,
- Chickenpox,
- Cold sores,
- Skin conditions around the eyes,
- Generally inflamed skin conditions,
- Rosacea (a skin condition affecting the face, commonly known as "rosy cheeks"),
- Acne,
- Dermatitis around the mouth,
- Genital itching,
- Shingles (a severe skin disease caused by the herpes zoster virus),
- Other skin infections,
- Widespread plaque-type psoriasis,
- Tuberculosis (TB),
- Syphilis (a sexually transmitted infection),

Use TERBISIL® PLUS with caution in the following cases:

- TERBISIL® PLUS is for topical use only.
- Do not apply TERBISIL® PLUS to your face.
- Do not use this cream to treat mouth infections, nor should it be ingested.
- TERBISIL® PLUS may irritate the eyes. Avoid applying it near your eyes or letting your hands (which have cream on them) come into contact with your eyes. If the cream accidentally gets into your eye, wipe it off and rinse your eye thoroughly with water. If any symptoms persist, consult your doctor.
- If you experience blurred vision or other visual disturbances, consult your doctor.
- If irritation or sensitivity develops during treatment, stop using TERBISIL® PLUS and seek medical advice for further treatment.
- If you have a bacterial skin infection in addition to the fungal infection, your doctor may prescribe another medication to treat the bacterial infection alongside TERBISIL® PLUS.
- When topical corticosteroids are used under occlusive dressings, for long periods, at high doses, or over large areas—especially when used in children—there is a significant risk of systemic absorption and side effects. Therefore, do not use TERBISIL® PLUS over large areas or under occlusive dressings. Special care should

be taken when using in areas such as the armpits or groin, as these areas are more sensitive to side effects.

- Children may be more susceptible to hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome (a condition caused by excessive corticosteroid use, characterized by weight gain, round face, and high blood pressure) from topical corticosteroids than adults, due to the higher surface area of their skin relative to their body weight.
- Corticosteroids used topically in children should be limited to the lowest effective dose. Chronic corticosteroid treatment may affect children's growth and development.
- The absorption of potent topical corticosteroids into the bloodstream may cause symptoms of Cushing's syndrome (such as fat accumulation in the back, a rounded face, excessive hair growth, and bone loss, particularly in the waist and pelvis), increased blood sugar, and sugar in the urine. Therefore, use with caution if you have diabetes.
- Side effects seen with oral or injected corticosteroids may also occur with topical corticosteroids.
- If you have had allergic reactions or side effects (e.g., thinning skin) to other topical or oral corticosteroids in the past, inform your doctor.
- Smoking or exposing TERBISIL® PLUS to an open flame should be avoided, as it may pose a serious risk of burning. Fabrics (such as clothing, bedding, or dressings) that have come into contact with TERBISIL® PLUS can catch fire easily and pose a significant fire hazard. Washing clothes and bedding may reduce, but not completely eliminate, this risk.
- Fungal or yeast infections can be transmitted to others. Be sure to use personal towels and clothing (preferably made of cotton) and avoid sharing them with others. To prevent reinfection, change your clothes daily and wash them frequently in very hot water.

If any of these warnings have applied to you in the past, consult your doctor.

Use of TERBISIL® PLUS with food and drink:

There are no restrictions on using TERBISIL® PLUS with food or on an empty stomach, as far as its method of application is concerned.

Pregnancy:

Consult your doctor or pharmacist before using the medication.

- TERBISIL® PLUS should not be used during pregnancy unless absolutely necessary.
- If you find out that you are pregnant during your treatment, immediately consult your doctor or pharmacist.

Breastfeeding:

Consult your doctor or pharmacist before using the medication.

- Since terbinafine hydrochloride can pass into breast milk, TERBISIL® PLUS should not be used during breastfeeding.
- Additionally, babies should not be allowed to come into contact with any treated skin area, including the breast.

Ability to drive and use machines:

TERBISIL® PLUS does not affect your ability to drive or operate machinery.

Important information about some of the ingredients of TERBISIL® PLUS:

TERBISIL® PLUS contains substances called cetyl alcohol and stearyl alcohol. These substances may cause local skin reactions (e.g., contact dermatitis).

Use with other medications:

There are no known interactions between TERBISIL® PLUS and other medications.

If you are currently using, or have recently used, any prescription or over-the-counter medications, please inform your doctor or pharmacist.

3. How to use TERBISIL® PLUS?

- **Instructions for proper use and dosage/application frequency:**

You should use TERBISIL® PLUS as directed by your doctor. Unless otherwise recommended by your doctor, apply TERBISIL® PLUS to the affected skin area once a day in a thin layer.

Improvement in the inflamed or eczematous skin should begin within a few days of treatment with TERBISIL® PLUS. The treatment duration should not exceed 10 days. This duration should be strictly followed, especially for lesions (tissue damage) in the groin and genital areas.

Avoid using large amounts over extended periods (especially on skin surfaces that come into contact with each other, such as the groin or armpit areas), as this can increase the risk of side effects.

Do not let TERBISIL® PLUS come into contact with your eyes.

If you do not observe any signs of improvement within 10 days of starting the treatment, consult your doctor or pharmacist.

After applying the medication to the affected area, wash your hands, as otherwise, you may spread the infection to other areas of your own skin or to others.

To ensure successful treatment, keep the affected skin area clean. Do not scratch the affected area. Scratching may cause further damage to the skin, slow the healing process, or spread the infection.

- **Route and method of application:**

Apply TERBISIL® PLUS in a thin layer to the affected skin area. Gently rub the cream into the skin. After application, wash your hands, as otherwise, you may spread the infection to other areas of your skin or to others.



- **Use in Different Age Groups:**

Use in children:

The combination of mometasone furoate and terbinafine hydrochloride should not be used in children under 16 years of age.

Its use is not recommended in infants and young children unless absolutely necessary.

Use in the elderly:

The use of TERBISIL® PLUS in the elderly has not been studied.

- **Special Usage Conditions:**

Kidney / Liver Insufficiency:

The use of strong topical corticosteroids for prolonged periods, over large surface areas, or under occlusive dressings (bandages), or in patients with concurrent liver insufficiency, may lead to systemic absorption and reversible suppression of the Hypothalamic-Pituitary-Adrenal (HPA) axis.

If you feel that the effect of TERBISIL® PLUS is too strong or too weak, please consult your doctor or pharmacist.

If you have used more TERBISIL® PLUS than you should:

Use TERBISIL® PLUS as recommended by your doctor.

If you have used more TERBISIL® PLUS than you should, consult your doctor or pharmacist.

If you forget to use TERBISIL® PLUS:

If you forget to apply TERBISIL® PLUS, apply it as soon as you remember, and then continue your treatment as usual.

Do not apply a double dose to make up for a missed dose.

Effects when treatment with TERBISIL® PLUS is stopped:

If you have been using TERBISIL® PLUS for a long time and your skin condition improves, do not suddenly stop using the cream. Abruptly stopping treatment may cause your condition to worsen. If you stop suddenly, you may notice redness of the skin and a burning or stinging sensation. Unless instructed by your doctor, do not discontinue treatment abruptly. Your doctor will gradually reduce the frequency of use until the treatment is fully stopped.

4. Possible Side Effects:

Like all medicines, TERBISIL® PLUS may cause side effects in individuals who are sensitive to any of its ingredients.

If you experience any of the following, stop using TERBISIL® PLUS immediately and seek emergency medical attention or contact the nearest hospital emergency department:

- **Unknown frequency:**
 - Allergic reaction symptoms (rash, difficulty breathing, swelling of the face, lips, tongue, or throat). These are very serious side effects.

If any of these occur, you may have a serious allergic reaction to TERBISIL® PLUS and may need emergency medical treatment or hospitalization.

The following frequency categories have been used:

- Very common: may affect more than 1 in 10 people.
- Common: may affect less than 1 in 10 but more than 1 in 100 people.
- Uncommon: may affect less than 1 in 100 but more than 1 in 1000 people.
- Rare: may affect less than 1 in 1000 but more than 1 in 10,000 people.
- Very rare: may affect less than 1 in 10,000 people.
- Unknown: frequency cannot be determined based on available data.

Common side effects:

- Itching
- Scaling or peeling of the skin

Uncommon side effects:

- Pain at the application site
- Irritation at the application site
- Skin lesions
- Crusting
- Change in skin color (pigmentation disorders)
- Redness of the skin
- Burning sensation on the skin

Rare side effects:

- Dry skin
- Contact dermatitis (a skin disease caused by contact with irritants like soaps, cosmetics, jewelry, etc.)
- Eczema (itchy skin inflammation caused by various factors)
- Worsening of skin condition
- Eye irritation

Very rare side effects:

- Burning sensation
- Inflammation of hair follicles (alopecia)

Unknown frequency:

- Allergic skin reactions
- Infection (inflammatory microbial diseases)
- Boils
- Numbness
- Blurred vision
- Bacterial and secondary skin infections
- Acne
- Hair follicle infection
- Thinning of the skin
- Heat rash-like red spots
- Stinging sensation
- Tingling sensation
- Increased hair growth
- Softening and cracking of the skin

Other unwanted effects reported with topical corticosteroid treatments include dry skin, irritation, dermatitis (a type of skin disease), perioral dermatitis, and small enlarged blood vessels, skin softening.

If you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting side effects:

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. Storage of TERBISIL® PLUS:

Keep out of the sight and reach of children.

Store TERBISIL® PLUS at room temperature below 25°C. Do not freeze.

Use in accordance with the expiration date on the packaging.

Do not use TERBISIL® PLUS after the expiration date on the packaging.

Do not throw away expired or unused medicine in the trash! Dispose of it through the collection system specified by the Ministry of Environment and Urbanization.

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This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]