

PATIENT INFORMATION LEAFLET

TERBISIL® 1% spray, solution
For topical use.

- **Active Substance:** 1 ml spray contains 10 mg terbinafine hydrochloride.
- **Excipients:** Cetomacrogol 1000, propylene glycol, ethanol (96%), deionized water.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.
- Follow these instructions exactly as written. Do not use higher or lower dose other than your recommended dose.

In this leaflet:

1. **What is TERBISIL® and what is it used for?**
2. **What you need to know before you use TERBISIL®**
3. **How to use TERBISIL®?**
4. **Possible side effects**
5. **How to store TERBISIL®?**

1. What is TERBISIL® and what is it used for?

TERBISIL® is available as a clear, particle-free solution in a 30 ml colored glass bottle packed in a box.

The active ingredient of TERBISIL® is terbinafine hydrochloride. TERBISIL® is a medicine effective against fungal diseases. TERBISIL® is a medicine that is effective by killing or by stopping the reproduction some fungi that cause skin problems.

TERBISIL® is used to treat fungal infections such as Athlete's foot (Tinea pedis), jock itch (Tinea cruris), ringworm (Tinea corporis), prickly heat (candidiasis) and Pityriasis versicolor.

2. What you need to know before you use TERBISIL®

DO NOT USE TERBISIL® in the following conditions

If:

- You have hypersensitivity (allergy) to terbinafine or any of the ingredients in TERBISIL®.

TAKE SPECIAL CARE with TERBISIL® in the following conditions

If:

- TERBISIL® is for topical use only.

- Do not spray to your face.
- In case of accidental contact with eyes, rinse thoroughly with running water and consult a physician if any symptoms persist.
- In case of accidental inhalation, consult a physician if any symptoms develop or persist.
- TERBISIL[®] contains propylene glycol, which may cause local skin irritation.
- Due to its alcohol content, TERBISIL[®] may be irritating on wounds.
- It may cause toxic epidermal necrolysis. In addition, skin irritation and sensitivity can be observed.
- Since fungal and yeast infections can be transmitted from one person to another, be sure to use your own towels and clothes and do not share them with others. To protect yourself against re-infection, towels and clothing should be washed frequently.

Please consult your doctor even if these warnings apply to you at any time in the past.

Taking TERBISIL with food and drink

Due to the method of administration of TERBISIL[®], there is no harm in taking it with meals or on an empty stomach.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

Consult your doctor before starting treatment with TERBISIL[®] if you are pregnant or might be pregnant. TERBISIL[®] should not be used during pregnancy unless clearly necessary.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

Do not breastfeed your child if you use TERBISIL[®].

Avoid contact of infants with treated areas, including breasts.

Driving and using machinery

The application of TERBISIL[®] to the skin does not affect your ability to drive and use machinery.

Important information on some excipients of TERBISIL[®]

TERBISIL[®] contains propylene glycol. This substance may cause irritation on the skin.

Taking with other medicines

Do not apply other medicinal products on the areas treated with TERBISIL[®].

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How to use TERBISIL®?

Instructions for proper use and dosage/administration frequency:

Apply TERBISIL® on infected skin areas as specified below:

- Athlete's foot (Tinea pedis): Once a day for one week.
- Jock itch (Tinea cruris) and ringworm (Tinea corporis): Once a day for one week.
- Prickly heat (cutaneous candidiasis): Once or twice a day for one week.
- Pityriasis versicolor: Twice a day for one week.

Although the infection may appear to be better at the end of a few days, continue to use the spray for the recommended duration of treatment. The infection may return if the spray is not applied regularly or stopped early.

If you do not observe any signs of improvement within 1 week of treatment, consult your doctor or pharmacist.

Route and method of administration:

Apply the spray as described below:

- Cleanse and dry the affected skin and surrounding area(s) thoroughly and wash your hands.
- Remove the cap of the bottle.
- If using the medicine for the first time, press the pump a few times until you achieve an even spray.
- For manipulation of the spray pump the bottle can be held in the upright or inverted position.
- Apply an adequate amount of spray to thoroughly wet the affected skin and surrounding area.
- Replace the cap of the bottle.
- Wash your hands otherwise you can spread the infection to other parts of your skin or to others.

To ensure the success of the treatment, wash the affected skin area regularly to keep it clean. Dry your skin by gently tapping and without rubbing. Do not scratch the area even if it is itchy, as this may cause further damage to the skin and slow down the healing process or spread the infection.

Different age groups

Use in children:

The safety of use in children has not been demonstrated.

TERBISIL® is not recommended in children and adolescents (under 16 years).

In elderly:

TERBISIL® may also be used in patient older than 65.

Special conditions of use:

Renal / Hepatic Failure:

There is no data on dosage adjustment in patients with renal and hepatic failure.

Follow these instructions unless otherwise recommended by your doctor.

Your doctor will inform you on the duration of your treatment with TERBISIL®. Do not stop treatment before the recommended duration as stopping TERBISIL® may cause your illness getting worse.

If you have the impression that the effect of TERBISIL® is too strong or weak, talk with your doctor or pharmacist.

If you use more TERBISIL® than you should

Contact your doctor or pharmacist if you or someone else, especially a child has accidentally swallowed a large amount of TERBISIL®. They will tell you what needs to be done.

If you have used more TERBISIL® than was prescribed, tell your doctor or pharmacist.

If you forget to use TERBISIL®

If you miss an application, apply the spray as soon as possible then carry on as before. If you only remember at the time of your next application, just apply the spray and carry on as normal.

Use the spray as described in this leaflet. Missed applications could risk the infection returning.

Do not take a double dose to make up for a forgotten dose.

Effects that may occur if you stop using TERBISIL®

Stopping treatment with TERBISIL® may cause your illness getting worse.

Do not stop treatment unless otherwise indicated by your doctor.

4. Possible side effects

Like all medicines, TERBISIL® may cause side effects in patients sensitive to its ingredients.

Following side effects may occur as a result of the use of TERBISIL®.

Side effects are listed as defined by following categories:

Very common: may be seen in at least 1 of 10 patients;

Common: may be seen in less than one of 10 patients but more than one of 100 patients

Uncommon: may be seen in less than one of 100 patients but more than one of 1,000 patients.

Rare: may be seen in less than one of 1,000 patients.

Very rare: may be seen in less than one of 10,000 patients

Frequency not known: Number of patients cannot be estimated from available data.

If you notice any of the following side effects, tell your doctor:

Common:

- Flaking or peeling skin (skin exfoliation)
- Itching (Pruritis)

Uncommon:

- Skin lesion
- Scab
- Skin disorder
- Skin color changes (pigmentation disorder)

- Redness of skin (erythema)
- Burning sensation
- Pain
- Pain at the site of application.
- Irritation at the site of application.

Rare:

- Eye irritation
- Dry skin
- Skin rash and itching (contact dermatitis)
- Skin rash with itching, redness and burning (eczema)
- Worsening of your skin's condition.

Not known:

These side effects are based on post-marketing experience and cannot be calculated using available data.

- Allergic reaction (hypersensitivity)
- Skin rash

These are mild side effects of TERBISIL®.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

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. How to store TERBISIL®?

Store TERBISIL® in original packaging and keep out of the reach and sight of children.

Store at room temperature below 30°C.

Do not refrigerate and do not freeze.

Use in compliance with the expiry date.

Do not use TERBISIL® after the expiry date which is stated on the packaging.

Do not use TERBISIL® if you notice defects on the product and/or its packaging.

Do not throw away drugs that have expired or are not used. Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

SANTA FARMA ILAC SAN. A.S. H. Edip Adivar / Boru Cicegi Sokak No: 16 Sisli, Istanbul, Türkiye

Tel: (+90 212) 220 64 00

Fax: (+90 212) 222 57 59

Manufacturer:

Kocaeli, Gebze, V (Kimya) Ihtisas OSB Erol Kiresepi Cad. No: 8, Dilovası, Kocaeli, Türkiye

Tel: (+90 262) 674 23 00

Fax: (+90 262) 674 23 21

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