

PACKAGE LEAFLET: INFORMATION FOR THE USER

TEKFIN 1% Cream

Applied externally on the skin

Active substance: Each gram of cream contains 10 mg of terbinafine hydrochloride.

Excipients: Benzyl alcohol, sodium hydroxide, sorbitan monostearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate, deionized water

Read all of this PACKAGE LEAFLET carefully before you start using 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet:

- 1. What TEKFIN is and what it is used for**
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1. WHAT TEKFIN IS AND WHAT IT IS USED FOR

The active ingredient of TEKFIN is terbinafine hydrochloride. TEKFIN is an effective drug against fungal diseases. TEKFIN is a drug that is effective against some fungi that cause skin problems and shows its effect by killing these fungi or by stopping their reproduction.

TEKFIN is used in the treatment of fungal infections such as Athlete's foot (Tinea pedis), Dhobie itch (Tinea cruris), ringworm (Tinea corporis), rash (Candidiasis) and Pityriasis versicolor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TEKFIN

Do not use TEKFIN

- if you are hypersensitive (allergic) to terbinafine or any other ingredients of TEKFIN.

Take special care with TEKFIN

- TEKFIN is for external use only.
- Do not apply TEKFIN to your face.
- TEKFIN may irritate the eyes. If the cream accidentally gets into your eyes, wipe the cream off and rinse your eyes thoroughly with running water and consult your doctor if any symptoms persist.
- Wash your hands after applying the cream.



- TEKFIN contains cetyl alcohol and stearyl alcohol that may cause local skin reactions.
- Since fungal and yeast infections can be transmitted to other people, be careful to use your own towels and clothes and do not share them with others. To protect yourself against re-infection, frequent washing of towels and clothes is necessary.

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

Using TEKFIN with food and drink

Due to the route of administration of TEKFIN, there is no interaction with food and drink.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or think you may be pregnant, consult your doctor before starting TEKFIN treatment. TEKFIN should not be used during pregnancy unless absolutely necessary.

If you realize that you are pregnant during the treatment consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

If you are using TEKFIN, do not breastfeed your baby.

Avoid contact of infants with the treated areas, including the breasts.

Driving and using machines

Application of TEKFIN to the skin does not affect your ability to drive and use machines.

Important information about some of the ingredients of TEKFIN

TEKFIN contains ingredients named cetyl alcohol and stearyl alcohol. These ingredients can cause local skin reactions (e.g., contact dermatitis).

Taking other medicines

Do not apply other medicinal products to the areas treated with TEKFIN cream.

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

3. HOW TO USE TEKFIN

Instructions for proper use and dose/frequency of administration:

Apply TEKFIN to infected skin areas as follows:

- Athlete's foot (Tinea pedis): Once a day for a week.
- Dhobie itch (Tinea cruris) and ringworm (Tinea corporis): Once a day for a week.
- Rash (Candidiasis): Once or twice a day for a week.
- Pityriasis versicolor: Once or twice a day for two weeks.

Continue to use the cream for the recommended treatment period, even if the infection improves after a few days. If the cream is not applied regularly or stopped early, the infection may recur.

Your skin condition should begin to improve within a few days of starting treatment with TEKFIN. But once the infection has improved, it will take longer for the damaged skin to heal completely.



The effects of TEKFIN will continue even after the end of the treatment period and your skin will continue to heal.

If you do not observe any signs of improvement within 2 weeks from the start of treatment, consult your doctor or pharmacist.

Route and method of administration:

Apply the cream as follows:

- Clean the affected skin and surrounding area(s) and wash your hands.
- The first time you use the tube, it will be sealed. Pierce the seal using the pointed tip at the top of the cap.
- Squeeze a small amount of cream onto your finger.
- Close the cap of the tube.
- Apply a thin layer of cream to the affected skin and directly to the surrounding area.
- Rub in gently.
- Wash your hands, otherwise you may spread the infection to other parts of your skin or to other people.

When used between the toes, under the breasts, buttocks or on the groin, the treated area may be covered with a light, fresh gauze strip, especially at night.

If the affected skin is between your fingers or toes or between your buttocks, chest or armpit or in the groin area, you can cover the area with gauze after applying the cream. This is especially recommended when lying down. If you are using gauze, use a new, clean cloth each time you apply the cream.

To ensure the treatment is successful, keep the affected skin area clean by washing it regularly. Dry your skin gently and without rubbing. Do not scratch the area, even if it itches, as this can further damage the skin and slow down the healing process or spread the infection.

Different age groups

Use in children

The safety of its use in children has not been conclusively proven. TEKFIN is not recommended for use in children under 16 years of age.

Use in elderly (65 years and over)

TEKFIN can also be used by patients over the age of 65.

Use in special conditions

Kidney/Liver impairment

There are no data on dose adjustment in patients with renal and hepatic impairment.

Follow these instructions unless your doctor recommends otherwise.

Your doctor will tell you how long your treatment with TEKFIN will last. Do not stop treatment early, because stopping TEKFIN treatment may cause your disease to get worse.

If you feel that the effect of TEKFIN is too weak or too strong, consult your doctor or pharmacist.



If you use more TEKFIN than you should

If you accidentally put more cream on your skin than you were told, simply wipe it off. This will not harm you.

If you or someone else, especially a child, accidentally swallows a large amount of TEKFIN, consult your doctor or pharmacist immediately. They will tell you what needs to be done.

If you use more TEKFIN than you should, talk your doctor or pharmacist.

If you forget to use TEKFIN

If you forget a dose, apply the cream as soon as you notice it and then continue as usual. If you remember when it's time for the next dose, apply the normal amount and then continue as usual.

Use the cream as stated in this leaflet. If you skip applications, the infection may reappear.

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

Possible effects when you stop using TEKFIN

Stopping TEKFIN treatment may cause your disease to get worse.

Do not interrupt treatment unless directed by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, there may be side effects in people who are sensitive to the substances contained in TEKFIN.

The following side effects may occur as a result of using TEKFIN:

Side effects are listed as shown in the following categories:

- | | |
|-------------|--|
| Very common | : may occur in at least 1 in 10 patients. |
| Common | : may occur in less than 1 in 10 patients, but more than 1 in 100 patients. |
| Uncommon | : may occur in less than 1 in 100 patients, but more than 1 in 1,000 patients. |
| Rare | : may occur in less than 1 in 1,000 patients. |
| Very rare | : may occur in less than 1 in 10,000 patients. |

Tell your doctor if you notice any of the following:

Common

- Skin flaking or peeling (skin exfoliation)
- Itching (pruritus)

Uncommon

- Skin lesion
- Crusting
- Skin disease
- Change in skin color (pigmentation disorder)
- Redness of the skin (erythema)
- Burning sensation on the skin
- Pain
- Pain at the application site
- Irritation at the application site

Rare

- Eye irritation
- Skin dryness
- Skin rash and itching (contact dermatitis)
- Skin rash (eczema) with itching, redness and burning sensation
Your skin condition may worsen.

Frequency not known:

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

- Allergic reaction (hypersensitivity)
- Skin rash

These are the mild side effects of TEKFIN.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

If you experience any undesirable effects not listed in this package leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE TEKFIN

Keep TEKFIN out of the reach and sight of children and in its original package.
Store at room temperature below 25°C.

Keep the tube tightly closed.

Use it in accordance with the expiry date.

Do not use TEKFIN after the expiry date shown on the pack.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder

DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No: 1
34303 Küçükçekmece - ISTANBUL/TURKEY

Manufacturer

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Kapaklı / Tekirdağ / TURKEY

This package leaflet was last revised on 21.11.2017.