MEDICATION GUIDE

TERBINAFINE (ter' bin a feen) hydrochloride Tablets

What is the most important information I should know about Terbinafine tablets?

Terbinafine tablets may cause serious side effects, including:

- **Liver problems that can lead to the need for a liver transplant or death**. This can happen in people who have liver problems and in people who have never had liver problems. Tell your doctor right away if you get any of these symptoms of liver problems:
  - nausea
  - poor appetite
  - tiredness
  - vomiting
  - upper right stomach-area (abdomen) pain
  - yellowing of your skin or eyes (jaundice)
  - dark (tea-colored) urine
  - pale or light colored stools

  Your doctor should do a blood test to check you for liver problems before you start treatment with Terbinafine tablets. Your doctor may also check you for liver problems during treatment, and tell you to stop taking Terbinafine tablets if you develop liver problems.

What are Terbinafine tablets?

Terbinafine tablets are a prescription medicine used to treat fungal infections of the fingernails and toenails (onychomycosis). Your doctor should do tests to check you for fungal infection of your nails before you start Terbinafine tablets. It is not known if Terbinafine tablets are safe and effective in children for the treatment of onychomycosis.

Who should not take Terbinafine tablets?

Do not take Terbinafine tablets if you:

- have had a severe allergic reaction to terbinafine hydrochloride when taken by mouth.
- have had liver disease for a long time (chronic) or have active liver disease.

What should I tell my doctor before taking Terbinafine tablets?

Before taking Terbinafine tablets, tell your doctor about all of your medical conditions, including if you:

- have or had liver problems
- have a weakened immune system (immunocompromised)
- have lupus (an autoimmune disease)
- are pregnant or plan to become pregnant. It is not known if Terbinafine tablets will harm your unborn baby. You should not start taking Terbinafine tablets during pregnancy.
- are breastfeeding or plan to breastfeed. Terbinafine passes into your breast milk and may harm your baby. You should not breastfeed while taking Terbinafine tablets. Talk to your doctor about the best way to feed your baby if you take Terbinafine tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Terbinafine tablets may affect the way other medicines work and other medicines may affect how Terbinafine tablets work.

How should I take Terbinafine tablets?

- Take Terbinafine tablets exactly as your doctor tells you to take it.
- Terbinafine tablets come as a tablet that you take by mouth.
- Terbinafine tablets are usually taken:

    - **1 time each day for 6 weeks to treat fungal infections of your fingernail, or**
    - **1 time each day for 12 weeks to treat fungal infections of your toenail**
- Terbinafine tablets can be taken with or without food.
- If you miss a dose of Terbinafine tablets, take it as soon as you remember. If it is less than 4 hours before your next dose, skip the missed dose. Just take the next dose at your regular time.
- If you take too many Terbinafine tablets, call your doctor. You may have the following symptoms:
    - nausea
    - stomach-area (abdomen) pain
    - frequent urination
    - rash
    - headache
    - vomiting
    - dizziness

What should I avoid while taking Terbinafine tablets?

Avoid sunlight. Terbinafine tablets can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You can get a severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your doctor if you get sunburn.

What are the possible side effects of Terbinafine tablets?

Terbinafine tablets may cause serious side effects, including:

- **See "What is the most important information I should know about Terbinafine tablets?"**
- **Change in your sense of taste or loss of taste** is common with Terbinafine tablets, but can also be severe. This may improve within several weeks after you stop taking Terbinafine tablets, but may last for a long time or may become permanent. Tell your doctor if you develop any of the following:
    - change in your sense of taste or loss of taste
    - poor appetite
    - weight loss
    - anxiousness
    - change in your mood or depressive symptoms. See the list of depressive symptoms below.
- **Change in your sense of smell or loss of smell** may happen with Terbinafine tablets. This may improve after you stop taking Terbinafine tablets, but may last for a long time or may become permanent. Tell your doctor if you have a change in your sense of smell or loss of smell.
- **Depressive symptoms. Tell your doctor right away if you develop any of these signs or symptoms:**
    - feel sad or worthless
    - change in sleep pattern
    - mood changes
    - loss of energy or interest in daily activities
    - restlessness
- **Low white blood cell count.** Terbinafine tablets may decrease your white blood cell count, especially neutrophils. You may have a higher risk of getting an infection when your white blood cell count is low.
- **Serious skin or allergic reactions, which may include problems with some of your body organs. Tell your doctor right away or get emergency medical** help if you get any of these symptoms:
    - skin rash
    - hives
    - sores in your mouth, or your skin blisters and peels
    - swelling of your face, eyes, lips, tongue or throat
    - trouble swallowing or breathing
    - fever
    - swollen lymph glands

- Also tell your doctor about any new symptoms, such as cough, chest pain, fast heartbeat, or blood in your urine.
- **New or worsening lupus.** Stop taking Terbinafine tablets and tell your doctor if you get any of the following:
  - a skin rash that gets worse (progresses), is scaly, red, shows scarring, or loss of skin color
  - unusual sensitivity to the sun that can cause a rash
- **Blood clotting problems.** When taking Terbinafine tablets, you may develop a blood clotting problem. Tell your doctor, if you get any unexplained bleeding or bruising.

The most common side effects of Terbinafine tablets include:
- headache
- diarrhea
- rash
- upset stomach
- abnormal liver function tests
- itching
- nausea
- stomach-area (abdomen) pain
- gas

These are not all of the possible side effects of Terbinafine tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Terbinafine tablets?
- Store Terbinafine Tablets at 20° - 25°C (68° - 77°F) [See USP Controlled Room Temperature].
- Keep Terbinafine tablets in a tightly closed container and keep out of the light.

Keep Terbinafine tablets and all medicines out of the reach of children.

General information about the safe and effective use of Terbinafine tablets.

Medicines are sometimes prescribed for purposes other than those listed in Medication Guide. Do not use Terbinafine tablets for a condition for which it was not prescribed. Do not give Terbinafine tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about Terbinafine tablets that is written for health professionals. For more information, call 1-800-367-3395 or go to www.bpirx.com.

What are the ingredients in Terbinafine tablets?

Active ingredient: terbinafine hydrochloride

Inactive ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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