**Patient Information Leaflet**

TERBINOL**® Tablets**

Terbinafine 250 mg tablets

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you have questions or if you experience side effects that are not listed in this leaflet, contact your doctor, jour pharmacist or your health care provider. Do not give this medicine to other people.**

1. **What is TERBINOL®  and what it is used for**

TERBINOL® belongs to a group of medicines called antifungal drugs, used for the treatment of fungal infections of the groin area, the skin (ring worm), toe and finger nails (yellow, opaque and thickened nails) and the feet (athlete’s foot) (ATC code: D01BA02).

1. **What you need to know before you take TERBINOL® Tablets**

***Do not take TERBINOL® Tablets*** if you are allergic (hypersensitive) to terbinafine or to any of the other ingredients (listed in section 6) or if you suffer from severely impaired **liver** or **kidney** function.

***Pregnancy and breast−feeding:*** if you are pregnant or breast-feeding do not take TERBINOL® Tablets, unless your doctor decides it is necessary.

***Taking other medicines:*** Always tell your doctor or pharmacist if you are taking any other medicines. This means medicines you have bought yourself as well as medicines on prescription from your doctor.It is especially important to tell your doctor about the following: Rifampicin (an antibiotic); Cimetidine (to treat stomach ulcers); tricyclic antidepressants, selective serotonin reuptake inhibitors and monoamine oxidase inhibitors; Triazolam (a sedative); Amiodarone, beta blockers, other antiarrhythmic drugs (heart medicines); Warfarin (to thin your blood); Ciclosporin (to prevent and treat the rejection of transplants and also used in immune diseases); Tolbutamine (for diabetes); Terfenadine (an antihistamine); oral contraceptives; Fluconazole, Ketoconazole (to treat fungal infections); caffeine.

***Driving or using machinery****:* some people have reported feeling dizzy or giddy while they are taking TERBINOL® Tablets. If you feel like this you should not drive or operate machinery.

1. **How to take TERBINOL®  Tablets**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Swallow the tablets **with water.** Do not exceed the recommended dose.

* Adults and children more than 40 kg: 1 Terbinol® 250 mg Tablet once daily
* Children from 20 to 40 kg: 1/2 Terbinol® 250 mg Tablet once daily
* For Children from 12 to 20 kg Terbinol® 250 mg Tablet are not recommended, because the tablets cannot be divided in 4 to obtain a daily dosage of 62,5 mg.
* For children under the age of 2 year there are no data available

The duration of treatment varies according to the indication and the severity of the infection: **the fingernails:** 6 weeks; **the toenails:** 12 weeks (some cases may require treatment for up to 6 months; complete resolution of the signs and symptoms of infection may not occur until several weeks after completing of the treatment: a healthy nail may take several months to grow back); **the head:** 4 to 6 weeks; **the groin area, skin:** 2 to 4 weeks; **the feet:** 2 to 6 weeks; **Pityriasis versicolor (= tinea versicolor):** 2 weeks.

**If you took more TERBINOL® Tablets than you should,** contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include headache, feeling sick, pain in the upper part of the stomach and dizziness. **If you forget to take a TERBINOL® tablet,** take the next tablet at the right time. Do not take a double dose to make up for a forgotten dose.

1. **Possible side effects**

**Contact your doctor immediately if you notice any of the following:**

* Impaired liver function or liver failure including reduction in liver enzymes, yellowing of the skin or whites of the eyes, inflammation of the liver and blocked bile flow. Symptoms include itching, constantly feeling sick, loss of appetite, tiredness, being sick, fatigue, stomach pain, dark urine or pale stools.
* An allergic (hypersensitivity) reaction with swelling of the face, lips, tongue or throat, difficulty breathing or swallowing or skin reactions such as a rash or pale or red irregular raised patches with severe itching (hives).
* A skin reaction such as a severe form of skin rash with flushing, fever, blisters or ulcers, severe rash involving reddening, peeling and swelling of the skin resembling severe burns, circular, irregular red patches on the skin of the hands and arms, sensitivity to sunlight or artificial light.
* Fever or sore throat**.**

**Other side effects** that occur frequently (more than 1 in 10 people treated) are gastro-intestinal intolerance symptoms like loss of appetite, taste disturbances and loss of taste sense, feeling of fullness, indigestion, feeling sick, mild stomach pain, diarrhoea. Also frequently reported (from 1 to 10 in 100 people treated) are symptoms of general discomfort like joint and muscle pain, feeling of general discomfort, headache, fever, fatigue

**If you experience side effects that are not listed above, contact your doctor, jour pharmacist or your health care provider.**

1. **How to store TERBINOL® Tablets:** Store below 30°C, in the original package, protected from light. Keep out of reach and sight of children. Do not use after the expiry date, stated on the package (Exp.). The expiry date refers to the last day of that month.
2. **Other information**

**What TERBINOL® Tablets** **contains:** 250 mg Terbinafine. Other ingredients: Hypromellose (Methocel E15-LV), Croscarmellose Sodium, Microcrystalline Cellulose PH 101, Microcrystalline Cellulose PH 102, Colloidal Silicon Dioxide, Magnesium Stearate and Purified Water, evaporated during production.

**TERBINOL® Tablets** is presented in a blister of 14one face notched table.

**TERBINOL® Tablets** is a prescription only medicine.

Name of Manufacturer: Nobel İlaç Sanayii ve Ticaret A.Ş., Sancaklar 81100 Düzce, Turkey.

Registration/Licence Holder: **Dafra Pharma GmbH**, Mühlenberg 7, 4052 Basel, Switzerland.

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