

## TERAFAN®

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

### Information about TERAFFAN

TERAFAN is available as:

-TERAFAN tablet for oral use containing 250 mg terbinafine (as terbinafine HCl) with the following excipients: starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, talc

-TERAFAN cream for topical use containing 1% terbinafine HCl with the following excipients: vaseline, emulsifying wax, paraffin oil, MP, PP, purified water

-TERAFAN spray solution for topical use containing 1% terbinafine HCl with the following excipients: propylene glycol, MP, PP, purified water.

Terbinafine is an allylamine derivative having a broad spectrum antifungal activity. TERAFFAN acts through inhibition of fungal ergosterol synthesis, an essential component of fungal cell membranes. It is fungicidal against dermatophytes, and some yeasts.

**TERAFAN tablets** are indicated in the treatment of fungal infections of the skin, scalp and nails:

-Onychomycosis of the toenail and fingernail (fungal infection of the nail)

-Dermatophytosis (fungal infections of the skin and scalp caused by dermatophytes: tinea capitis, tinea corporis, tinea cruris, interdigital and plantar tinea pedis)

-Cutaneous candidiasis

**TERAFAN cream and spray** are indicated in the treatment of fungal infections of the skin:

-Dermatophytosis: interdigital tinea pedis (athlete's foot), tinea corporis (ringworm), tinea cruris (jock itch) caused by *Trichophyton* (e.g. *T. rubrum*, *T. mentagrophytes*, *T. verrucosum*, *T. violaceum*) and *Epidermophyton floccosum*

-Cutaneous candidiasis

-Pityriasis versicolor

Terafan spray may be sprayed in shoes to decontaminate shoes insoles colonized by *Trichophyton rubrum*

### The way to take TERAFFAN

TERAFAN should be administered as directed by your doctor.

To help clear up your infection completely, it is very important that you keep taking this medicine for the prescribed treatment period, even if your symptoms begin to clear up or you begin to feel better after a few days. Since fungal infections may be very slow to clear up, stopping your medication too soon can cause the symptoms and the fungal infection to flare up again.

#### **TERAFAN tablets:**

The usual recommended dose for adults is 250 mg (1 tablet) once daily preferably during meals. TERAFFAN tablets may be administered for children aged over 2 years for the treatment of tinea capitis (usually for 2 to 4 weeks):

-in children weighing 10 to 20 kg: 62.5 mg (a quarter of a tablet of 250 mg) once daily

-in children weighing 20 to 40 kg: 125 mg (half a tablet of 250 mg) once daily

-in children weighing over 40 kg: 250 mg (one tablet) once daily

#### **TERAFAN cream:**

TERAFAN cream can be applied once or twice daily. The affected areas should be cleansed and dried thoroughly before application. The cream should be applied to the affected skin and surrounding area in a thin layer and rubbed in lightly. In the case of intertriginous infections (submammary, inguinal) the application may be covered with a gauze strip, especially at night.

**TERAFAN Spray:**

TERAFAN Spray is applied once or twice daily, for 1 or 2 weeks. The affected areas should be cleansed and dried thoroughly before application. A sufficient amount of spray solution should be applied to wet the treatment area thoroughly, and to cover the affected skin and surrounding area.

**Duration of treatment:**

The duration of treatment varies with the indication and is dependent on the severity of the infection:

Indication	Oral treatment	Topical treatment	
		Dosage	Duration
Fingernail onychomycosis	6 to 12 weeks	-	-
Toenail onychomycosis	12 to 24 weeks	-	-
Tinea capitis	2 to 4 weeks	-	-
Tinea pedis (interdigital and plantar type)	2 to 6 weeks	1 application per day	1 to 2 weeks
		2 applications per day	1 week
		1 spray per day	1 week
Tinea corporis, cruris	2 to 4 weeks	1 application per day	1 week
		1 spray per day	1 week
Cutaneous candidiasis	2 to 4 weeks	1 application per day	1 to 2 weeks
		1 spray per day	1 to 2 weeks
Pityriasis versicolor	-	1 -2 applications per day	2 weeks
		2 sprays per day	1 week

In onychomycosis, the optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail tissue.

**In case of overdose**

In case of intake of high doses of this medication, or if the spray or the cream have been ingested, or in case of accidental inhalation inform your doctor at once and seek emergency medical attention. General measures should be adopted.

**In case of missed dose**

Take or apply the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take or apply a double dose at once.

**Contraindications**

This drug is contraindicated in case of known hypersensitivity to any of the components and in case of severe hepatic or renal impairment.

**Precautions**

- Oral dosage should be adjusted in patients with impaired renal function.
- This drug should not be used in patients with existing liver disease. Liver function tests are recommended before starting oral therapy.
- Report to your doctor any symptoms of persistent nausea, anorexia, fatigue, vomiting, jaundice, dark urine, pale stool or skin rash.
- Inform your doctor before using this medication in case of pregnancy or lactation. It is recommended not to initiate treatment with this drug during pregnancy or lactation.
- TERAFAN cream and spray are for external use only. Avoid contact with the eyes. In case of accidental ocular contact, rinse thoroughly with water.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

The tablets must be used with caution with rifampicin or cimetidine.

For topical products, it is recommended that other medicinal products are not applied on the treated areas.

**Adverse reactions**

This drug is generally well tolerated when used as directed. Side effects are usually mild and transient.

The most reported adverse effects after oral use are gastrointestinal disturbances such as nausea, diarrhea, and mild abdominal pain. Other effects may include taste and smell disturbances, headache, liver dysfunction, dizziness, hematological disorders or skin reactions.

Minor symptoms such as redness, itching or stinging have been rarely reported at the site of application of topical products.

Inform your doctor if any of these effects appears or becomes bothersome.

**Storage**

Store at controlled room temperature, protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

TERAFAN TABLETS, pack of 14 tablets

TERAFAN CREAM, tube of 15g

TERAFAN SPRAY, spray bottle of 15 ml

**Revision date: 04/2011**

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