# Skinabin®

Terbinafine Hydrochloride

## Composition

**Skinabin®** 250 tablet: Each tablet contains Terbinafine Hydrochloride BP equivalent to Terbinafine 250 mg.
**Skinabin®** cream: Contains Terbinafine Hydrochloride BP equivalent to Terbinafine 1% w/w.

## Pharmacology

**Skinabin®** is the preparation of Terbinafine Hydrochloride. Terbinafine is an allylamine antifungal. It inhibits biosynthesis of ergosterol, an essential component of fungal cell membrane, via inhibition of squalene epoxidase enzyme. This results in fungal cell death primarily due to the increased membrane permeability mediated by the accumulation of high concentrations of squalene but not due to ergosterol deficiency. Depending on the concentration of the drug and the fungal species test *in vitro*, Terbinafine Hydrochloride may be fungicidal. Terbinafine has been shown to be active against most strains of the following microorganisms both *in vitro* and in clinical infections: *Trichophyton mentagrophyte, Trichophyton rubrum.*

## Indication

Fungal infections of the skin caused by dermatophytes such as *Trichophyton rubrum, Trichophyton mentagrophytes, Microsporum canis* and *Epidermophyton floccosum.*

### Tablet

**Skinabin®** tablets are indicated for the treatment of-

- Onychomychosis of the toenail or fingernail due to dermatophytes.
- Ringworm (Tinea corporis, Tinea cruris and Tinea pedis) where oral therapy is considered appropriate due to the site, severity or extent of the infection.

### Cream

**Skinabin®** cream is indicated for the treatment of-

- Yeast infections of the skin principally caused by the genus Candida (e.g. *Candida albicans*)
- Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*)

## Dose and administration

*Route of administration:* **Skinabin®** can be taken orally and topicaly.

### Tablet

The recommended dose of **Skinabin®** tablet is 250 mg once daily (duration of treatment varies according to the indication and the severity of infections). In case of 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.

| Indication | Duration |
|---|---|
| Onychomycosis of fingernail | 6 weeks |
| Onychomycosis of toenail | 12 weeks |
| Tinea pedis | 2-6 weeks |
| Tinea corporis | 4 weeks |
| Tinea cruris | 2-4 weeks |

### Cream

**Skinabin®** cream can be applied once or twice daily (duration of treatment varies according to the indication and the severity of infections). Cleanse and dry the affected areas thoroughly before application of cream. Apply the cream to the affected skin and surrounding area in thin layer and rub in lightly. Relief of clinical symptoms usually occurs within a few days. The treatment must be used regularly and for an adequate length of time. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there is no sign of improvement after two weeks, the diagnosis should be verified.

| Indication | Duration |
|---|---|
| Tinea pedis | 1 week |
| Tinea corporis, Tinea cruris | 1-2 weeks |
| Cutaneous candidiasis | 2 weeks |
| Pityriasis versicolor | 2 weeks |

Lorem ipsum

## Contraindication

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## Warning and precaution

Liver failure, sometimes leading to liver transplant or death, has occurred with the use of oral terbinafine. Terbinafine tablets should be discontinued if liver injury develops. Taste and smell disturbance have been reported with the use of terbinafine tablets. Terbinafine tablets should be discontinued if taste and smell disturbance occurs. Depressive symptoms have been reported with terbinafine use. Prescribers should be alert to the development of depressive symptoms. Severe neutropenia has been reported with terbinafine use. If the neutrophil count is less than or equal to 1000 cells/mm$^3$ terbinafine tablets should be discontinued. Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, exfoliative dermatitis, bullous dermatitis, and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome have been reported with oral terbinafine use. If progressive skin rash occurs, treatment with terbinafine tablets should be discontinued. Terbinafine cream is for external use only. Contact with the eyes should be avoided.

## Side effects

The most common side effects of terbinafine are redness, headache, diarrhea, rash, dyspepsia, liver enzyme abnormalities, pruritus, taste disturbance, nausea, abdominal pain and flatulence. Side effects of cream include occasional redness, itching or stinging at the site of application; symptoms must be distinguished from allergic which are rare but require discontinuation of treatment.

## Use in pregnancy and lactation

**Pregnancy:** Terbinafine is pregnancy category B drug. There are no adequate and well controlled studies in pregnant women. It is recommended that terbinafine not to be initiated during pregnancy unless the benefits outweighs the risk to the fetus.

**Lactation:** Terbinafine is present in breast milk of nursing mothers. Treatment with terbinafine is not recommended in women who are nursing.

## Use in children and adolescents

The safety and efficacy of terbinafine tablet have not been established in pediatric patients with onychomycosis. The safety and efficacy of terbinafine cream have not been established in pediatric patients.

## Drug interaction

**Drug interaction with medications:** Terbinafine is an inhibitor of the CYP450 2D6 isoenzyme and has an effect on metabolism of desipramine, cimetidine, fluconazole, cyclosporine, rifampin and caffeine.There is no known drug interaction when terbinafine is taken topically.

**Drug interaction with food and others:** Not applicable.

## Overdose

Overdose with oral terbinafine is limited. Doses up to 5 grams have been taken without inducing serious adverse reactions. The symptoms of overdose included nausea, vomiting, abdominal pain, dizziness, rash, frequent urination and headache.

## Storage

Store in a cool (below 30º C) and dry place protected from light. Keep away from the reach of children.

## Packing

**Skinabin®** 250 tablet: Carton of 14 tablets in blister.
**Skinabin®** cream: Tubes of 5 g and 15 g.

® Registered Trade Mark

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