

Only for the use of Medical Professionals

# Skinabin®

Terbinafine Hydrochloride

## Description

**Skinabin®** is the preparation of Terbinafine Hydrochloride. Terbinafine is an allylamine with a range of antifungal activity. It is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Terbinafine is either fungicidal or fungistatic against yeasts, depending on the species. Terbinafine interferes with fungal ergosterol biosynthesis by inhibiting squalene epoxidase in the fungal cell membrane at an early stage. This leads to a deficiency in ergosterol and to intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine is highly effective in fungal infections of the skin, hair and nails caused by *Trichophyton spp.*, *Microsporum spp.* and *Epidermophyton floccosum*. It is also effective against yeast infections of the skin, principally those caused by the genus *Candida*. Topical Terbinafine appears to be effective in pityriasis versicolor due to *Pityrosporum orbicularis*.

## Indications

**Skinabin®** cream is indicated for the treatment of the following dermatological infections: interdigital tinea pedis (athlete's foot), tinea cruris (jock itch) or tinea corporis (ring worm) due to susceptible organisms and planter tinea pedis (moccasin type) due to *Trichophyton spp.*

## Dosage and administration

**Adults:** **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 a thin layer and rub it lightly.

Condition	Duration of treatment
Tinea pedis	1 week
Tinea corporis, tinea cruris	1-2 weeks
Cutaneous candidiasis	2 weeks
Pityriasis versicolor	2 weeks

Relief of clinical symptoms usually occurs within 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 are no signs of improvement after two weeks the diagnosis should be verified.

**Children:** The safety and efficacy of terbinafine has not been established in pediatric patients.

**Elderly:** Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy.

## 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 benefit outweighs the risk to the fetus.

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

## Side effects

The most common side effects of terbinafine are redness, itching or stinging at the site of application. Symptoms must be distinguished from allergic reactions which are rare but do require discontinuation of the treatment.

## Contraindications

Terbinafine is contraindicated in patients with known hypersensitivity to terbinafine or any other components of this product.

## Warnings and precautions

Terbinafine cream is for external use only. Contact with the eyes should be avoided.

## Drug interactions

There are no known drug interactions when terbinafine is taken topically.

## Overdose

There has been no experience of overdose with topical formulation of terbinafine.

## Pharmaceutical precautions

Store in a cool (below 30°C) and dry place protected from light.

## Presentation

**Skinabin®** cream: It contains Terbinafine Hydrochloride BP equivalent to Terbinafine 1% w/w.

## Package quantities

**Skinabin®** cream: Tubes of 5 g and 15 g.

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