

OVER DOSE:

No case of over dosage has been reported with Terbisil Cream/Lotion, however, If Terbisil Cream/Lotion ingested inadvertently, adverse effects similar to those observed with an over dosage of Terbisil tablets (e.g. headache, nausea, epigastric pain and dizziness) are to be expected.

PHARMACODYNAMICS:

Terbinafine is an allylamine which has a broad spectrum of antifungal activity in fungal infections of the skin caused by dermatophytes such as *Trichophyton* (e.g. *T. rubrum*, *T. mentagrophytes*, *T. verrucosum*, *T. violaceum*), *Microsporum canis*, and *Epidermophyton floccosum*. Even at low concentrations, terbinafine is fungicidal against dermatophytes and molds. The activity against yeasts is fungicidal (e.g. *Pityrosporum obiculare* or *Malassezia furfur*) or fungistatic, depending on the species.

Terbinafine interferes specially with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol, and to an intracellular accumulation at squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane. The enzyme squalene epoxidase is not linked to the cytochrome P450 system. Terbinafine does not influence the metabolism of hormones or other drugs.

Terbisil Cream/Lotion has a rapid onset of action, and can be effective with a short treatment duration.

PHARMACOKINETICS:

Less than 5% of the dose is absorbed after topical application to humans; systemic exposure is thus very slight.

PRESENTATION:

Terbisil cream is available in 10g Alu tube.

Terbisil lotion is available in 20ml plastic bottle.

INSTRUCTIONS:

For external use only.

Store between 15°C - 30°C.

Protect from light.

Keep out of the reach of children.

To be sold on the prescription of a registered medical practitioner only.

ہدایات:-

ٹرہبیل کریم/لوشن صرف بیرونی استعمال کے لئے ہے۔

دوا کو 15°C سے 30°C درجہ حرارت کے درمیان رکھیں۔

دوا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔ روشنی سے بچائیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

Terbisil

Cream
Lotion

(Terbinafine HCl B.P 1%)

ٹرہبیل کریم/لوشن

(ٹرہبنافین ایچ سی ایل بی۔ پی 1%)

COMPOSITIONS:• **Terbisil Cream:**

Each tube contains Terbinafine HCl B.P1% w/w

Product complies with J.P Specs.

• **Terbisil Lotion:**

Each gram contains Terbinafine HCl B.P10mg

Product complies with J.P Specs.

THERAPEUTIC INDICATIONS:

- Fungal infections of the skin caused by dermatophytes
- Pityriasis (tinea) versicolor
- Yeast infections of the skin, principally those caused by the genus *Candida* (e.g., *C. albicans*)

DOSAGE & APPLICATION:

The duration of treatment varies according to the indication and the severity of the infection. Terbisil Cream/Lotion can be applied once or twice daily. Cleanse and dry the affected areas thoroughly before treating with Terbisil Cream/Lotion. Apply the cream/Lotion to the affected skin and surrounding area in a thin layer and rub it lightly. In the case of intertriginous infections (submammary, interdigital, intergluteal, inguinal) the application may be covered with gauze, especially at night.

Likely duration of treatment:

Tinea corporis, *T. cruris* & *Tinea pedis*: 1 week once a day

Cutaneous candidiasis: 1week once a day , Pityriasis versicolor: 1 week twice a day

If there are no signs of improvement after 2 weeks, the diagnosis should be verified.

USE OF TOPICAL TERBISIL IN THE ELDERLY:

There is no evidence to suggest that elderly patients require different dosages or experience side effects different from those in younger patients.

USE OF TOPICAL TERBISIL IN CHILDREN:

Experience with Terbisil Cream/Lotion in children is limited, and its use cannot, therefore, be recommended.

CONTRAINDICATIONS:

Known hypersensitivity to terbinafine or any of the excipients contained in the formulation.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE:

Terbisil Cream/Lotion is for external use only. It may be irritating to the eyes. In the case of accidental contact with the eyes, rinse eyes thoroughly with running water. Terbisil Cream/Lotion like all medicines should be kept out of the reach of children.

INTERACTIONS:

No drug interactions are known with Terbisil Cream/Lotion.

PREGNANCY AND LACTATION:

Animal studies did not reveal any teratogenic or embryofetotoxic potential of terbinafine. No case of malformations in humans has been reported with Terbisil to date. However, since clinical experience in pregnant women is very limited, topical Terbisil should be used only if clearly indicated during pregnancy. With the treatment of Terbisil Cream/Lotion, the small amounts absorbed through skin and unlikely to affect the Infant. Nursing mothers should not apply Terbisil Cream/Lotion to the breast

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