

**RIDSIL OINTMENT**

**Active Ingredient:**  
Terbinafine HCl ..... 1%/w

**Presentation:**  
Jars of 10g and 15g.

**Product Descriptions:**  
White to off-white, smooth, non-greasy moisturizing based ointment.

**Pharmacology:**  
Terbinafine is an allylamine derivative reported to have a broad-spectrum antifungal activity. It is considered to act through inhibition of fungal sterol synthesis. It works by preventing the formation of substances needed by the fungus to grow and develop, which causes weakness and death of the fungus. Terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi and some yeast. It kills dermatophytes such as *Trichophyton* (e.g. *T. rubrum*, *T. mentagrophytes*, *T. verrucosum*, *T. violaceum*), *Microsporum canis* and *Epidermophyton floccosum* and Pityriasis versicolor due to *Pityrosporum orbiculare*. It is also used to treat cutaneous candidiasis.

Fungicidal concentrations in nails are maintained for several weeks after therapy is discontinued. Skin concentrations may be up to 75-fold higher than those in the blood. It may persist in the skin for up to 8 weeks after the antifungal has been discontinued.

**Indications:**  
For the treatment of fungal infections of the feet, groin and body including athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis), Pityriasis versicolor and fungal nail infection (cutaneous candidiasis).

**Directions of Use:**  
Clean and dry the affected area thoroughly with warm water before application. Apply the ointment thinly and evenly onto the affected area once daily.

Duration of treatment is one to two weeks. To prevent recurrence, continue to treat the area for one to two weeks after signs or symptoms of infections have gone. Treatment can be repeated if necessary.

**Symptoms and Treatments of Overdose:**  
Symptoms of a Terbinafine overdose are not well known. The adverse effects observed in humans suggest that the main symptoms in cases of accidental ingestion would be gastrointestinal, e.g. nausea and vomiting. Gastric lavage and / or symptomatic supportive treatment may then be required.

**Contraindications:**  
Not suitable for patients with known hypersensitivity to Terbinafine.

**Precautions:**  
For external use only. Avoid in contact with eyes, nose and mouth. Not to be taken.  
Clinical symptoms usually disappear in a few days. Irregular application or premature discontinuation of the treatment increases the risk of relapse. If no sign of healing can be detected at the end of one week, the diagnosis should be reviewed.  
In the event of skin lesions, use this product with care because it contains alcohol which can irritate.

**Use in Pregnancy and Lactation:**  
Category B. Reproduction studies carried out on animals have not revealed any risk for the foetus but no controlled study has been carried out on pregnant women. In the case of local application of Terbinafine, less than 5% of the applied amount is absorbed. The use of Terbinafine by pregnant women or those who are breastfeeding is not recommended unless the expected benefit appreciably outweighs the potential risk.  
Terbinafine only passes into maternal milk in small quantities. It is not known whether this small amount in the maternal milk can have a harmful effect on the infant.

**Interactions with Other Medicaments:**  
Terbinafine does not generally affect the concentration of other medicines. However, care should be taken when using together with other topical medicines as other topical medicines may affect the absorption or effectiveness of Terbinafine application.

**Undesirable Effects:**  
Terbinafine is generally well-tolerated. Occasionally, itching or redness may occur at the area of application.

**Storage:**  
Store below 30°C. Protect from light. Keep cap tightly closed. Keep out of reach of children. Jauhkan daripada capaian kanak-kanak.

**Shelf Life:**  
3 years from the date of manufacture.

Manufacturer and Product Registration Holder  
**WINWA MEDICAL SDN. BHD.**  
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Size: 75mm x 105mm  
■ Dark Blue (Pantone 2767U)