

## ▶ TERBINAFINE - SAFE PRESCRIBING - NAIL IT

1

- ▶ BE AWARE THAT TERBINAFINE CAN CAUSE SERIOUS ADVERSE REACTIONS
- ▶ ADVISE PATIENTS TO REPORT SYMPTOMS OF HEPATOTOXICITY AND ANY SKIN REACTIONS
- ▶ ALWAYS CONFIRM PRESENCE OF SUSCEPTIBLE FUNGAL ORGANISMS BEFORE PRESCRIBING
- ▶ CONSIDER THE BENEFITS OF TERBINAFINE AGAINST POTENTIAL FOR HARM

Oral terbinafine is indicated for dermatophyte infections of the nails (onychomycosis) and skin where oral therapy is appropriate (eg due to the site, severity or extent of infection). If pharmacological treatment is appropriate, oral terbinafine is usually considered first line but its use is associated with a number of rare, but potentially serious adverse reactions.

### **BE AWARE THAT TERBINAFINE CAN CAUSE SERIOUS ADVERSE REACTIONS**

The most frequently reported adverse effects associated with oral terbinafine are gastrointestinal including abdominal discomfort, anorexia, nausea and diarrhoea. Rashes (eg urticaria) can also occur, sometimes associated with arthralgia or myalgia. Headache has also been reported in 1-10% of patients.

Serious adverse reactions include hepatotoxicity, blood dyscrasias, including agranulocytosis and severe neutropenia.

Liver function tests (LFTs) and full blood count (FBC) should be monitored at baseline and after 4 to 6 weeks of treatment. Serious adverse reactions usually occur within 1 to 2 months of starting oral terbinafine, and will often resolve within a week of ceasing therapy. However some reactions, including loss or alteration of taste can be prolonged.

Some adverse reactions such as blood dyscrasias, can be life-threatening. and there have also been deaths attributable to terbinafine therapy.

### **ADVISE PATIENTS TO REPORT SYMPTOMS OF HEPATOTOXICITY AND ANY SKIN REACTIONS**

Advise patients taking terbinafine to be alert for the symptoms of infection or neutropenia (eg fever, sore throat, mouth ulcers), symptoms suggestive of liver impairment (eg abdominal pain, jaundice, persistent nausea), and any other reaction associated with terbinafine including progressive skin rash, taste perversion or loss, or hair loss.

Patients, especially those who have been taking terbinafine for more than one month, should report these symptoms promptly so that clinical investigations including blood tests can be arranged urgently and terbinafine therapy stopped immediately. A delay in diagnosis is likely to be associated with an increase in morbidity and mortality.

### **ALWAYS CONFIRM PRESENCE OF SUSCEPTIBLE FUNGAL ORGANISMS BEFORE PRESCRIBING**

Terbinafine should only be used when there is a clear indication for its use, and empirical therapy should be avoided. Complications of nail infections are uncommon but may occur in patients who have diabetes, underlying vascular disease or connective tissue disorders.

To maximise the safety and efficacy of oral terbinafine, ensure that the infection is caused by a susceptible fungal organism before prescribing this medicine. Nail clippings or skin scrapings should be sent for microscopic examination and culture.

Other non-fungal conditions which may present with similar symptoms include trauma, lichen planus, and vascular disorders.

### **CONSIDER THE BENEFITS OF TERBINAFINE AGAINST POTENTIAL FOR HARM**

The benefits of using oral terbinafine to treat relatively common fungal infections of the skin or nails should be weighed against the risk of harm to the patient.

The implications of using terbinafine should be discussed with the patient, in particular, the long duration of treatment, the potential side-effects of treatment, and that there is no guarantee that terbinafine use will result in a cure.

If initial treatment fails; confirm mycology and check adherence to treatment. An alternative medicine may be more appropriate.

→ continued

## ▶ TERBINAFINE

2

The usual adult dose of terbinafine is 250 mg daily.

Duration of treatment depends on the site and extent of the infection. It is well absorbed orally with and without food and is concentrated in the skin and nails.

**Patients with renal impairment** (creatinine clearance less than 50 mL/min) should receive half the normal dose. Treatment should be avoided for patients with creatinine clearance less than 20 mL/min.

**Terbinafine is not recommended for patients with chronic or active liver disease**, psoriasis or systemic lupus erythematosus (SLE) because these conditions can be exacerbated.

Prescribers should be aware of clinically relevant medicine interactions before prescribing. These are listed in the data sheet and The New Zealand Formulary.

### **Pregnancy and breastfeeding.**

There is no human data for the use of terbinafine in pregnancy, so it is advisable to wait to begin treatment until after pregnancy. Terbinafine should not be administered to breastfeeding mothers as it is excreted into breast milk.

### **KEY REFERENCES**

1. New Zealand Formulary Terbinafine  
[http://www.nzf.org.nz/nzf\\_3341.html?searchterm=terbinafine](http://www.nzf.org.nz/nzf_3341.html?searchterm=terbinafine)  
(Accessed 12-10-18)
2. Rex Medical Limited. Terbinafine tablets data sheet 11-09-17.  
<http://www.medsafe.govt.nz/profs/Datasheet/d/deolatetab.pdf>  
(accessed 12-10-18)
3. Medsafe, Wellington. Medicines Adverse Reactions Committee 127<sup>th</sup> Meeting Minutes 14 September 2006; Oral Terbinafine Serious Adverse Reactions.  
<http://www.medsafe.govt.nz/Profs/adverse/Minutes127.htm#2.1.12> (accessed on 12-10-18)

### **ACKNOWLEDGEMENTS**

We wish to thank Dr Kerry Read, Infectious Diseases Consultant and Kristen Bondesio, Antimicrobial Stewardship Pharmacist at Waitemata District Health Board, for their valuable contribution to this bulletin.

[CLICK HERE FOR FURTHER INFORMATION ON TERBINAFINE AND A FULL REFERENCE LIST](#)

▶ For further information on other high-risk medicines visit our website at : [www.saferx.co.nz](http://www.saferx.co.nz)