IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 28 February 2007

Part 1. Product Information

a)	Title:	Terbinafine for Oral Use
b)	Product Name/Type:	Terbinafine for Oral Use - MIMS Advisory
c)	Active Substance:	Terbinafine
d)	Reference:	MIMS Publication Article - February 2007
e)	Prescription Required:	Yes

Part 2. Problem/Issue

a) Problem/Issue:

Terbinafine for Oral Use Terbinafine is a medicinal substance authorised in Ireland, for oral use, in the following indications: Fungal infections of the skin such as Tinea corporis, Tinea cruris and Tinea pedis caused by Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum) where oral therapy is considered appropriate due to the site, severity or extent of the infection. Onychomycosis (terbinafine-sensitive fungal infection of the nails) caused by dermatophytes. Terbinafine was first authorised for oral use in the early nineteens nineties and since that time the IMB has received a total of 97 reports of suspected adverse reactions associated with its use. These reported reactions have included a range of allergy-related effects such as erythema multiforme, as well as cases of systemic lupus erythematosus, hepatic reactions, anaemia and arthralgia. Therefore, and in view of the known risk of serious adverse reactions with the use of oral terbinafine, the IMB would like to remind prescribers of the following important safety information: The use of oral terbinafine is not recommended in patients with chronic or active liver disease. Before prescribing terbinafine pre-existing liver disease should be assessed. Hepatotoxicity may occur in patients with and without pre-existing liver disease. Patients prescribed terbinafine should be warned to immediately report any symptoms of unexplained persistent nausea, anorexia, fatigue, vomiting, right upper abdominal pain, or jaundice, dark urine or pale stools. Patients with these symptoms should discontinue taking oral terbinafine and the patient's liver function should be immediately evaluated. Patients with impaired renal function (creatinine clearance less than 50ml/minute or serum creatinine of more than 300 mmol/l) should receive half the normal dose of terbinafine. In vitro and in vivo studies have shown that terbinafine inhibits the CYP2D6 enzyme system. Therefore, patients receiving concomitant treatment with drugs predominantly metabolised by this enzyme, [e.g. certain members of the following drug classes: tricyclic antidepressants (TCAs), b-blockers, selective serotonin reuptake inhibitors (SSRIs), antiarrhythmics class IC and monoamine oxidase inhibitors (MAO-Is) Type B], should be closely monitored, particularly if the coadministered drug has a narrow therapeutic index. Patients on terbinafine who develop a high fever or sore throat should be examined for possible haematological reaction. Oral terbinafine should be used with caution in patients with psoriasis as in rare cases exacerbation of the psoriasis has occurred. Finally, healthcare professionals are reminded that any suspected adverse reactions should be reported to the IMB in the usual way.

Part 3. Keywords

a) Keywords:

Terbinafine