Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080

Tel 973 781 8300

NOVARTIS

May 2001

Dear Doctor:

Novartis Pharmaceuticals Corporation would like you to be aware of the following information for LAMISIL (terbinafine HCl) Tablets. LAMISIL Tablets should not be prescribed for patients with pre-existing liver disease. This information is now also reflected in the new prescribing information for LAMISIL Tablets.

1. Rare cases of hepatic failure, some leading to death or liver transplant, have occurred with the use of LAMISIL (terbinafine HCl) Tablets for the treatment of onychomycosis in individuals with and without preexisting liver disease. In the majority of liver cases reported in association with LAMISIL use, the patients had serious underlying systemic conditions and an uncertain causal relationship with LAMISIL. Although ongoing post-marketing surveillance and clinical trials have shown no increase in the frequency of these adverse events reported, it is important to reinforce the need for proper patient selection when considering treatment with LAMISIL Tablets. In response to these rare cases from post-marketing surveillance, Novartis Pharmaceuticals Corporation has revised the "WARNINGS," "PRECAUTIONS," and "ADVERSE REACTIONS" sections of the labeling.

   Most important for the prescriber is the addition of the following statements under PRECAUTIONS: "Lamisil is not recommended for patients with chronic or active liver disease. Before prescribing Lamisil Tablets, pre-existing liver disease should be assessed. Hepatotoxicity may occur in patients with and without pre-existing liver disease. Pretreatment serum transaminase (ALT and AST) tests are advised for all patients before taking Lamisil Tablets. Patients prescribed Lamisil (terbinafine HCl) Tablets should be warned to report immediately to their physician any symptoms of persistent nausea, anorexia, fatigue, vomiting, right upper abdominal pain, or jaundice, dark urine or pale stools (see WARNINGS). Patients with these symptoms should discontinue taking oral terbinafine, and the patient's liver function should be immediately evaluated." Please see full prescribing information enclosed for additional clarifications.

2. The Drug Interactions section of the labeling has been modified to include the following: "*In vitro* studies have also shown that terbinafine inhibits CYP2D6-mediated metabolism. This may be of clinical relevance for compounds predominantly metabolized by this enzyme, such as tricyclic antidepressants, ß-blockers, selective serotonin reuptake inhibitors (SSRIs), and monoamine oxidase inhibitors (MAO-Is) Type B, if they have a narrow therapeutic window.

3. In addition, it has come to the attention of Novartis that prescribing and dispensing errors have occurred involving LAMISIL (terbinafine HCl) Tablets and other drugs with similar sounding names including LAMICTAL (lamotrigene) Tablets.

   LAMICTAL is an antiepileptic. LAMISIL Tablets are indicated for onychomycosis (nail fungus) and are marketed as a 250-mg circular, biconvex, bevelled tablet bearing "Lamisil" on one side and "250" on the other side. The recommended dosage for LAMISIL Tablets is one 250 mg tablet daily for twelve weeks for toenails and six weeks for fingernails.

Sincerely,

Alan L. Bess, MD
Clinical Safety and Epidemiology

Stephen Cunningham, MD
Medical Affairs

Please see complete prescribing information for LAMISIL enclosed.

LMT-2065