Lamisil® (terbinafine) – New Warning

- On January 19, 2017, the FDA approved a new update to the *Warnings and Precautions* section of the Lamisil (terbinafine) tablet and Lamisil oral granule drug labels regarding thrombotic microangiopathy (TMA).

- Lamisil tablets are indicated for the treatment of onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium).

- Lamisil oral granules are indicated for the treatment of tinea capitis in patients 4 years of age and older.

- Cases of TMA, including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, some fatal, have been reported with terbinafine.

- Terbinafine should be discontinued if clinical symptoms and laboratory findings consistent with TMA occur. The findings of unexplained thrombocytopenia and anemia should prompt further evaluation and consideration of diagnosis of TMA.

- Other warnings and precautions of Lamisil tablets and oral granules include hepatotoxicity, taste disturbance including loss of taste, smell disturbance including loss of smell, depressive symptoms, hematologic effects, serious skin/hypersensitivity reactions, and lupus erythematosus.

    — In addition, Lamisil oral granules have a warning for laboratory monitoring.