GlaxoWellcome

IMMEDIATE ATTENTION REQUIRED

DISPENSING ERRORS ALERT

June 6, 2000

Dear Pharmacist:

Glaxo Wellcome Inc. has received reports of prescription dispensing errors involving **LAMICTAL**® (lamotrigine) Tablets and **LAMISIL**® (terbinafine hydrochloride) Tablets resulting in serious adverse events. The error reports involve dispensing Lamictal Tablets when Lamisil Tablets were prescribed and the reverse scenario.

Patients with epilepsy who do not receive their **antiepileptic drug LAMICTAL** due to a dispensing error would be inadequately treated and could experience serious consequences including status epilepticus. Conversely, patients erroneously receiving Lamictal instead of their **antifungal drug LAMISIL** would be unnecessarily subjected to a risk of potential side effects (including serious rash). This is especially true if patients receive an initial high dose of Lamictal (see Prescribing Information for Lamictal, DOSAGE AND ADMINISTRATION section).

LAMICTAL is an **antiepileptic** drug marketed as 25-, 100-, 150-, and 200-mg six-sided, shield-shaped tablets bearing "Lamictal" and the numeric representation of the strength (e.g., "Lamictal 150"). Lamictal Chewable Dispersible Tablets are 5-mg and 25-mg white tablets engraved with "GX CL2" and "GX CL5," respectively. To initiate therapy with Lamictal, the dose is titrated over a period of several weeks.

LAMISIL is an **antifungal** drug marketed as 250-mg circular, biconvex, bevelled tablets bearing "Lamisil" on one side and "250" on the other side. The recommended dosage for Lamisil is one 250-mg tablet daily for six or twelve weeks depending on the affected nail. Topical formulations of Lamisil are also available by prescription and over-the-counter.

Please be alert for both written and oral prescriptions for **LAMICTAL** and **LAMISIL**, and promptly share this letter with your pharmacy staff. Measures to avoid dispensing errors should be assessed (e.g., computer entry and filling of prescriptions, product shelving, patient counseling) and implemented as appropriate.

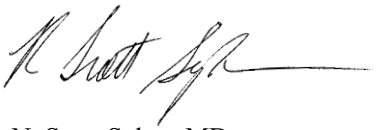
If you become aware of a prescription dispensing error involving these products, please contact the appropriate manufacturer (Glaxo Wellcome Inc.: 1-800-334-4135; Novartis Pharmaceuticals Corp.: 1-888-669-6682), the USP Medication Errors Reporting Program (1-800-233-7767) or the FDA MEDWATCH program by phone 1-800- FDA-1088, by FAX 1-800-FDA-0178, by modem 1-800-FDA-7737, or by mail:

MEDWATCH HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

For further information on Lamictal, please call 1-888-TALK-2-GW (1-888-825-5249).

Thank you.

Sincerely,



N. Scott Sykes, MD
Vice President
North American Product Surveillance

PLEASE CONSULT COMPLETE PRESCRIBING INFORMATION FOR LAMICTAL ENCLOSED.

Glaxo Wellcome Inc.

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