GlaxoWellcome



DISPENSING ERRORS ALERT

August 2000

Dear Health Professional:

Medication dispensing errors are a serious threat to quality health care and necessitate the combined efforts of prescribers, dispensers, manufacturers and patients to minimize their occurrence. Glaxo Wellcome Inc. has received reports of dispensing errors involving LAMICTAL® (lamotrigine) Tablets and other prescription drugs; most of these errors have been with the prescription medication LAMISIL® (terbinafine hydrochloride) Tablets, some of which have resulted in serious adverse events. Your assistance is requested in clearly communicating oral and written prescriptions for these two products to help avoid future dispensing errors. For example, you might consider, when appropriate, including the intended use on prescriptions for these products. Please alert patients for whom you are prescribing these medications that they should carefully check the medication they receive and promptly bring any questions or concerns to the attention of the pharmacist. Additional efforts to address this situation within pharmacies are under way.

The error reports involve dispensing **LAMISIL** Tablets when **LAMICTAL** Tablets were prescribed and the reverse scenario. Patients erroneously receiving either medication would be unnecessarily subjected to the risk of adverse events. In addition, patients with epilepsy who do not receive their antiepileptic drug due to a dispensing error would be inadequately treated and could experience serious consequences including status epilepticus. Patients erroneously receiving **LAMICTAL** instead of their antifungal drug **LAMISIL** would not have the dose of **LAMICTAL** properly titrated and would be unnecessarily subjected to a risk of potential side effects, including serious rash (see enclosed Prescribing Information for **LAMICTAL** Tablets, Warning section and Dosage and Administration section).

LAMICTAL is an antiepileptic drug marketed as 25-mg (white), 100-mg (peach), 150-mg (cream), and 200-mg (blue), shield-shaped tablets bearing "Lamictal" and the numeric representation of the strength (e.g., "Lamictal 150"). Lamictal Chewable Dispersible Tablets are 5mg and 25mg white tablets engraved with "GX CL2" and "GX CL5," respectively. **LAMISIL** is an antifungal drug marketed as 250-mg circular tablets bearing "Lamisil" on one side and "250" on the other side.

Clear communication when prescribing any drug product is an important measure in the effort to reduce the occurrence of dispensing errors. If you become aware of a prescription dispensing error involving **LAMICTAL**, please contact Glaxo Wellcome Inc. at 1-800-334-4153; 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 Internet http://www.fda.gov/medwatch or www.fda.gov/medwatch, or by mail:

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

Thank you. Sincerely,

Richard S. Kent, M.D.

Vice President US Medical Operations

hard S. te

PLEASE CONSULT COMPLETE PRESCRIBING INFORMATION FOR LAMICTAL ENCLOSED.