Rx Mix-Ups Prompt Reminyl Name Change

BY ELIZABETH MECHCATIE

Senior Writer

anssen Pharmaceutica has agreed to change the name of its Alzheimer's drug Reminyl in response to inadvertent dispensing of the oral blood glucose-lowering drug Amaryl in its place. The mix-ups have resulted in cases of severe hypoglycemia and other serious adverse events, including one fatality.

In a Dec. 22, 2004, letter, the Food and

Drug Administration acknowledged Janssen's intention to change the name of all Reminyl products.

At press time, the new name had not been announced.

Amaryl is the trade name for glimepiride, which is approved for treating type 2 diabetes and is marketed by Aventis. Reminyl has been the trade name for galantamine, which is approved for mild to moderate dementia of the Alzheimer's type and is marketed by Janssen Pharmaceutica.

Spontaneous reports submitted to the FDA and to the U.S. Pharmacopeia have described prescriptions that have been "incorrectly written, interpreted, labeled, and/or filled due to the similarity" between the two trade names, according to a "Dear Health Care Provider" letter issued by Janssen. The letter was posted on the FDA's MedWatch Web site (www.fda.gov/medwatch).

Making the confusion more likely is that both drugs come in 4-mg strengths and in tablet formulations. And because both generic names start with the letter g, the drugs may be stored near each other.

Prescriptions have been 'incorrectly written, interpreted, labeled, and/or filled due to the similarity' between the two trade names.

The starting dose Reminyl is 4 mg twice a day, while the starting dose of Amaryl is 1-2 mg twice a day, with a maximal starting dosage of 2 mg, the letter states.

Health care professionals who become aware of these

or any other medication errors should call the USP Medication Errors Reporting Program, at 800-23ERROR or 800-FAIL-SAF; or the FDA's MedWatch Adverse Event Reporting Program at 800-FDA-1088.

Errors also can be reported to the manufacturers: 800-526-7736 (Janssen) or 800-633-1610 (Aventis).

Sleep, Cognitive **Problems Could** Be Connected

BALTIMORE — Sleep disturbances are common in assisted-living facilities and may be linked to a variety of cognitive disorders, Patrick J. Raue, Ph.D., said in a poster session at the annual meeting of the American Association for Geriatric Psychiatry.

The researchers enrolled 198 assisted-living-facility residents who were chosen by randomly selecting room numbers from facilities that were randomly selected throughout Maryland. A specially designed 11-item questionnaire was used to identify symptoms of daytime sleepiness and insomnia. A consensus panel that included geriatric psychiatrists and nurses determined participant diagnoses.

Data showed that 66.5% of participants had dementia, and within this group 38% had no sleep disturbance and 62% had sleep disturbance of some kind, including insomnia (22%), excessive daytime sleepiness (23%), or both (17%), said Dr. Raue of the department of psychiatry at Cornell University, New York.

In participants with insomnia only, 45% had no dementia, 43% had Alzheimer's disease, 4% had vascular disease, and 9% had cognitive disorder not otherwise specified (NOS). In those with heightened symptoms of daytime sleepiness only, researchers found that 16% had no dementia, 44% had Alzheimer's disease, 34% had cognitive disorder NOS, and 6% had vascular disease. In participants who had both dementia and insomnia, 23% had Alzheimer's disease, 17% had vascular disease, 17% had cognitive disorder NOS, and 43% had none of these other ailments.

—Deeanna Franklin