

**IMPORTANT DRUG WARNING**

October 19, 2004

**IMPORTANT SAFETY ALERT REGARDING MEDICATION ERRORS**

Dear Pharmacist:

Janssen Pharmaceutica Products, L.P. and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. have recently been made aware of several reports of medication errors involving confusion between REMINYL®<sup>1</sup> (galantamine hydrobromide), a drug approved for the treatment of mild to moderate dementia of the Alzheimer's type, and AMARYL®<sup>2</sup> (glimepiride), a product of Aventis Pharmaceuticals Inc., indicated for the treatment of non-insulin-dependent (Type 2) diabetes mellitus. These reports include instances in which REMINYL was prescribed but AMARYL® was incorrectly dispensed and administered instead, leading to various adverse events including severe hypoglycemia and one death.

According to spontaneous reports submitted to the FDA and the United States Pharmacopoeia, prescriptions have been incorrectly written, interpreted, labeled, and/or filled due to the similarity in names between REMINYL and AMARYL®. These two products have an overlapping strength (4 mg) and an overlapping dosage form (tablets). In addition, both products have generic names (galantamine vs. glimepiride) that might lead to their storage in close proximity.

It is important to note that REMINYL has a starting dosage of 4 mg TWICE a day, whereas AMARYL® is initially dosed at 1-2 mg ONCE a day, with a maximum starting dosage of 2 mg.

REMINYL is supplied for oral administration as 4 mg (round, off-white), 8 mg (round, pink), and 12 mg (round, orange-brown) tablets. REMINYL tablets are imprinted "JANSSEN" on one side, and "G" and the strength "4", "8", or "12" on the other.

AMARYL® is supplied for oral administration as 1 mg (pink, flat-faced, oblong with notched sides at double bisect and imprinted with "AMARYL"), 2 mg (green, flat-faced, oblong with notched sides at double bisect and imprinted with "AMARYL") and 4 mg (blue, flat-faced, oblong with notched sides at double bisect, imprinted with "AMARYL").



We recognize that medication errors have multiple system causes and the pharmacist's role in avoiding such errors is pivotal. Your assistance and increased attention is requested in verifying and accurately dispensing oral and written prescriptions for these two products to help avoid future medication errors.

We offer the following suggestions to help decrease the potential for future errors:

- Place AMARYL® and REMINYL apart from one another on the shelf; we advise use of the enclosed "shelf talker" described below
- Confirm the brand name prescribed on written and oral prescriptions
- Counsel patients about the brand name, indication, and proper use of each medication

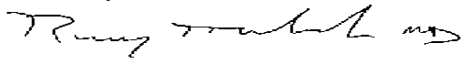
Janssen Pharmaceutica Products, L.P. has developed the following enclosed material for pharmacists to help prevent medication errors:

- A "shelf talker" that can be used to help differentiate REMINYL from other stocked merchandise

If you become aware of any medication errors involving REMINYL, report them immediately to us at 1-800-JANSSEN (526-7736), and if AMARYL is involved, to Aventis Pharmaceuticals at 1-800-633-1610. Medication errors should also be reported to the USP Medication Errors Reporting Program in cooperation with the Institute for Safe Medication Practices (1-800-23ERROR; 1-800-FAIL-SAF) or FDA's MedWatch Adverse Event Reporting Program (1-800-FDA-1088).

Thank you for your attention to this matter.

Sincerely,



Ramy Mahmoud, MD, MPH  
Vice-President, CNS  
Janssen Medical Affairs, LLC

PLEASE CONSULT ENCLOSED COMPLETE PRESCRIBING INFORMATION FOR REMINYL.

<sup>1</sup>REMINYL Prescribing Information, Janssen Pharmaceutica Products, L.P. March 2003

<sup>2</sup>AMARYL Prescribing Information, Aventis Pharmaceuticals Inc. August 2004