IMMEDIATE ATTENTION REQUIRED: DISPENSING ERROR ALERT REGARDING AMARYL® AND REMINYL® TABLETS

Dear Pharmacist,

Aventis has received reports of medication errors in which the oral sulfonylurea AMARYL® (glimepiride tablets) has been mistakenly dispensed to patients who have been prescribed REMINYL® (galantamine HBr). AMARYL® is used once daily in the treatment of type 2 diabetes mellitus. REMINYL® is an acetylcholinesterase inhibitor used twice daily in the treatment of Alzheimer's Dementia.

AMARYL® and REMINYL® share a common dosage strength of 4 mg. Reports have involved verbal or written REMINYL® prescriptions incorrectly interpreted, labeled or filled, with AMARYL® being dispensed. This situation may produce hypoglycemia in patients with Alzheimer's Disease and without diabetes mellitus and may result in confusion, loss of consciousness, coma, and even death.

In the event where REMINYL® has been dispensed in error for AMARYL®, diabetes patients would be at risk of hyperglycemia. The cholinergic side effects of REMINYL®, such as nausea, vomiting, and diarrhea, may be readily apparent.

In our efforts to encourage appropriate prescribing and treatment of diabetes patients with AMARYL® and to ensure the safety of all patients, we ask you to be observant when dispensing AMARYL® 4 mg to patients who are known to you to have Alzheimer's Disease, when filling a new prescription for AMARYL® 4 mg, or when this specific 4 mg dose of AMARYL® has not been previously administered/ prescribed for the individual patient. Please also note the unique shape, size, color and scoring of the AMARYL® tablets and the AMARYL® name embossed into the tablet.

To help prevent medication dispensing errors regarding AMARYL® and REMINYL®, we recommend the following precautions:

- Review patients' medical history when dispensing AMARYL® or REMINYL®, confirming, if possible, that patients receiving AMARYL do, in fact, have diabetes
- Review dosing frequency (AMARYL® is prescribed once a day; REMINYL® twice a day)
- Confirm the brand name prescribed
- Confirm new prescriptions for AMARYL® 4 mg, since the recommended starting dose is 1-2 mg
- Verify all verbal AMARYL® and REMINYL® prescription orders by asking the prescriber to spell the name and/or give the medication's indication

If you become aware of a prescription dispensing error involving AMARYL® or REMINYL®, please contact one of the following:

- USP-ISMP Medication Errors Reporting Program (www.ismp.org or www.usp.org or 1-800-FAIL-SAF (E))
- FDA MEDWATCH program (phone 1-800-FDA-1088, FAX 1-800-FDA-0178, Internet: www.fda.gov/medwatch or www.fda.gov/medwatch, or mail: FDA Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787)
- Aventis Pharmaceuticals at 1-800-633-1610, select option 2 for adverse event reporting (AMARYL)
- Janssen Pharmaceutica Products at 1-800-JANSSEN (526-7736) (REMINYL)

Aventis is concerned about the reports of dispensing errors. Your adherence to the precautions recommended above will help prevent such errors. Please share this information with your co-workers and staff. We look forward to your cooperation in continuing the safe and effective treatment of patients with diabetes mellitus.

AMARYL® retains a favorable safety profile – the incidence of hypoglycemia with AMARYL®, as documented by blood glucose values < 60 mg/dl, ranged from 0.9% to 1.7%. Other most common adverse reactions (≥ 1%) (n = 746) include dizziness (1.7%), asthenia (1.6%), headache (1.5%), and nausea (1.1%). As with all sulfonylureas, severe hypoglycemia may occur.

Sincerely,

Poul Strange, M.D., Ph.D.
Senior Medical Director, Metabolism
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PLEASE CONSULT THE ENCLOSED COMPLETE PRESCRIBING INFORMATION FOR **AMARYL®**.

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