FDA Alert for Healthcare Professionals

Galantamine hydrobromide (marketed as Razadyne, formerly Reminyl)

FDA ALERT [5/2005]: FDA and other international health authorities are reviewing data from two studies of Razadyne (galantamine) in the treatment of mild cognitive impairment because higher mortality rates were seen in drug-treated patients than placebo-treated patients. Based on this information, FDA has asked the manufacturer to revise the labeling.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of Razadyne, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Recommendations

Available information**,** including postmarketing data from the FDA's Adverse Event Reporting system (AERS) database**,** does not warrant changing prescription recommendations at this time. We wish to emphasize the following:

- Razadyne is approved as a treatment for mild to moderate Alzheimer's disease but not for mild cognitive impairment.

Data Summary

Two 2-year trials, involving 2,000 patients in 16 countries, studied whether Razadyne could slow progression to dementia in patients with mild cognitive impairment. Individuals with mild cognitive impairment demonstrate isolated memory impairment greater than expected for their age and education, but do not meet current diagnostic criteria for Alzheimer's disease; however, the majority of individuals with mild cognitive impairment do appear to develop overt Alzheimer's disease over time.

Follow-up information regarding deaths in these studies is available for about 88 percent of participants. Fifteen (1.5%) deaths in patients taking Razadyne and five (0.5%) deaths in patients taking placebo were reported during the double-blind portion of the two studies, either while taking study drug/placebo or within 30 days of study drug/placebo discontinuation. The causes of death in the 20 patients are similar to those commonly occurring in an older population, and were varied, with no single cause predominating.

Review of mortality and other safety data for these two trials is ongoing.

In a number of earlier clinical trials, none of which lasted longer than 6 months, in similarly-aged patients (including patients with Alzheimer's Disease), the incidence of deaths in those treated with Razadyne was no higher than in patients treated with placebo, and the incidence of deaths in those treated with placebo was far higher than in the trials of mild cognitive impairment, described above.