ORTHO-McNEIL
NEUROLOGICS, INC.

1125 Trenton-Harbourton Road
Titusville, New Jersey 08560

IMPORTANT PRESCRIBING INFORMATION

March 31, 2005

Dear Healthcare Professional:

The REMINYL® (galantamine hydrobromide) Prescribing Information has been updated with the addition of the following information regarding the results of two investigational studies of REMINYL in individuals with mild cognitive impairment. REMINYL is approved only for the treatment of mild to moderate Alzheimer's Disease. No indication is being sought for the treatment of individuals with mild cognitive impairment.

PRECAUTION

Deaths in Subjects with Mild Cognitive Impairment (MCI)

In two randomized, placebo-controlled trials of 2 years duration in subjects with mild cognitive impairment (MCI), a total of 13 subjects on REMINYL® (n=1026) and 1 subject on placebo (n=1022) died. The deaths were due to various causes which could be expected in an elderly population; about half of the REMINYL® deaths appeared to result from various vascular causes (myocardial infarction, stroke, and sudden death).

Although the difference in mortality between REMINYL® and placebo-treated groups in these two studies was significant, the results are highly discrepant with other studies of REMINYL®. Specifically, in these two MCI studies, the mortality rate in the placebo-treated subjects was markedly lower than the rate in placebo-treated patients in trials of REMINYL® in Alzheimer's disease or other dementias (0.7 per 1000 person years compared to 22-61 per 1000 person years, respectively). Although the mortality rate in the REMINYL®-treated MCI subjects was also lower than that observed in REMINYL®-treated patients in Alzheimer's disease and other dementia trials (10.2 per 1000 person years compared to 23-31 per 1000 person years, respectively), the relative difference was much less. When the Alzheimer's disease and other dementia studies were pooled (n=6000), the mortality rate in the placebo group numerically exceeded that in the REMINYL® group. Furthermore, in the MCI studies, no subjects in the placebo group died after 6 months, a highly unexpected finding in this population.

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.

These investigational trial results have been presented at international scientific meetings as well as in a press release, and also have appeared on Health Authority web sites in many countries of the world. Ortho-McNeil Neurologics, Inc.,* remains committed to providing you with the most current product information available for the management of your patients. Please refer to the enclosed package insert for full Prescribing Information. As always, we request that serious adverse events be reported to Ortho-McNeil Neurologics at 1-800-526-7736 or to the FDA MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or by email (www.fda.gov/medwatch). For additional medical information about REMINYL or any other Ortho-McNeil Neurologics, Inc. products, please call 1-800-526-7736 from 9AM to 5PM EST, Monday through Friday.

Sincerely,

Joseph Hulihan, MD
Vice President, Medical Affairs
Ortho-McNeil Neurologics, Inc.

* REMINYL was formerly marketed by Janssen Pharmaceutica Products, L.P., a sister company also headquartered in Titusville, N.J.