## Warning on Bismacine

The FDA is warning consumers and health care providers not to use a product called bismacine, also known as chromacine. The agency is investigating one report of a death and several reports of injury related to the administration of the substance.

Bismacine, an injectable product prepared by druggists, has been used by some to treat Lyme disease. But bismacine has not been approved by the FDA to treat Lyme disease or any other disease or condition.

Bismacine is not a pharmaceutical. It is suggested or administered by "alternative health" practitioners or by people claiming to be medical doctors. Bismacine contains high amounts of bismuth, a heavy metal used in some medications taken by mouth to treat a bacterium that can cause stomach ulcers (Helicobacter pylori). It is not approved for use by injection.

On April 20, 2006, one person died as a result of treatment with bismacine, and on March 29, 2005, another person was hospitalized after receiving a bismacine treatment. Other serious adverse events have been reported. Possible effects of bismuth poisoning include cardiovascular collapse and kidney failure.

The FDA is advising consumers and health care providers not to use bismacine. Individuals who believe they have suffered adverse events from receiving bismacine may wish to seek medical attention. The agency is evaluating the product suppliers and will take additional action as appropriate.

Adverse reactions experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online at *www.fda.gov/MedWatch/report.htm*; by phone (800) FDA-1088 (332-1088); by returning FDA form 3500, which may be downloaded from *www.fda.gov/MedWatch/getforms.htm*; by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787; or by fax (800) FDA-0178 (332-0178).

## First Treatment for Dementia of Parkinson's Disease

The FDA has approved Exelon (rivastigmine tartrate) for the treatment of mild-to-moderate dementia associated with Parkinson's disease, a disorder of the central nervous system. Exelon was approved previously for the treatment of mild-to-moderate dementia of the Alzheimer's type.

"It's been recognized for almost a decade that the dementia of patients with Parkinson's disease differs from the dementia of patients with Alzheimer's," says Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research. "But until now, there has been no treatment that has been shown to be effective specifically for the dementia associated with Parkinson's disease. Today's approval of Exelon helps to fill this medical need."

It is estimated that about 0.2 percent to 0.5 percent of people older than 65 are affected by Parkinson's dementia and experience such symptoms as impairments in executive function, memory, and attention. The approval of Exelon for the treatment of Parkinson's dementia is based on the results of a randomized, placebo-controlled clinical study with 541 patients who showed symptoms of mild-to-moderate dementia two years or later after their diagnosis for Parkinson's disease. At the end of the 24-week trial, the condition of the Exelon-treated patients, as shown on a scale that measures mental processes, was significantly better than the condition of the patients on placebo.

The use of Exelon has been associated with significant gastrointestinal adverse reactions. In clinical trials, 47 percent of the patients treated with the drug developed nausea, and others on high doses of Exelon experienced significant weight loss. Other common adverse events reported by patients on Exelon include vomiting, anorexia, dyspepsia, and loss of strength (asthenia). In some patients with Parkinson's disease, treatment with Exelon was associated with a worsening of tremor.

Exelon is manufactured by Novartis Pharmaceutical Corp. in East Hanover, N.J.

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