



BOXED WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. Prochlorperazine Edisylate Injection, USP is not approved for the treatment of patients with dementia-related psychosis (see **WARNINGS**).

If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported.

The presence of phenothiazines may produce false-positive phenylketonuria (PKU) test results.

Clinical studies of prochlorperazine did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects

Treatment

It is important to determine other medications taken by the patient since multiple drug therapy is common in overdose situations. Treatment is essentially symptomatic and supportive. Keep patient under observation and maintain an open airway, since involvement of the extrapyramidal mechanism may produce dysphagia and respiratory difficulty in severe overdose.

PROTECT FROM LIGHT. Store in the box until ready to use. Discard if markedly discolored.

 CAPLIN STERILES