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HALDOL® (haloperidol)

INJECTION

FOR USE AS AN ANTIEMETIC AGENT

McNeil Laboratories, Inc.
January, 1974

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INTRODUCTION

Nausea and vomiting can be an undesirable consequence of certain surgical procedures. Antiemetic medication is indicated to aid in the comfort of the patient and to help prevent postoperative complications that can result from uncontrolled emesis.

Watt and Keats (1) find antiemetics to be "clearly indicated whenever vomiting is severe enough to produce significant loss of fluid, electrolyte, nitrogen or sources of calories", and "to prevent esophageal damage from violent retching, prevent disruption of postoperative suture lines, and to prevent retching after cataract removal". Bellville (2) supports this view in his statement that "in most situations, if a patient is vomiting, treatment is indicated. The hazards associated with a single dose of most antiemetics are small indeed compared to the hazards and inconvenience of vomiting".

Phenothiazines have been used with various degrees of effectiveness as antiemetic agents, but even when effective their usefulness is often limited by side effects (3,4).

HALDOL has been used with growing success in place of phenothiazines for psychiatric disorders. It also has been shown previously to be an effective antiemetic in both animal (5) and human (3) apomorphine-induced emesis experiments. In addition, both double-blind and open clinical studies in Europe (6-15), not conducted under McNeil

sponsorship, support the effectiveness and safety of haloperidol as an antiemetic agent.

The studies reported herein were designed to evaluate the effectiveness and safety of HALDOL in the treatment of nausea and vomiting as a result of operative procedures and gastrointestinal disorders. These conditions were chosen for drug evaluation since they represent two widely diverse etiologies and permit adequate patient populations for evaluation. The rapid onset of action of parenteral HALDOL makes this formulation a means of providing therapy as rapidly as possible.

A number of phase II clinical studies were undertaken to demonstrate the safety and effectiveness of HALDOL as an antiemetic agent and to establish an effective dosage regimen. One of these studies was an extensive pharmacologic evaluation of HALDOL administered orally or parenterally in human subjects administered apomorphine to induce vomiting. Two additional studies evaluated HALDOL administered parenterally to determine effective dosages in patients with nausea and vomiting as a result of operative procedures.

The phase III clinical evaluation of HALDOL, administered intramuscularly as an antiemetic agent, was conducted in 16 well-controlled double-blind studies against placebo. Nine studies were conducted for the treatment of postoperative nausea and vomiting, and seven studies were conducted for the treatment of nausea and vomiting resulting from gastrointestinal disorders.