SYNOPSIS

TITLE A DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROLLED STUDY OF LACTULOSE IN THE TREATMENT OF ENCOPRESIS IN CHILDREN WITH CHRONIC CONSTIPATION

INVESTIGATORS Removed for privacy reasons

OBJECTIVES The primary objective of this study was to determine the efficacy of lactulose versus placebo in the abolition or reduction of encopresis due to chronic constipation in children. The secondary objective was to assess the safety and tolerance of lactulose in a pediatric population.

STUDY DESIGN This was a randomized, double-blind, parallel-group, placebo-controlled, flexible-dose, 2-center study. Efficacy was evaluated using physician-rated scales for constipation, encopresis, and clinical global improvement. A daily calendar and evaluation of a radiological abdominal examination provided supportive evidence of efficacy. Each patient was evaluated weekly during the four-week study design.

PATIENT POPULATION Patients were recruited from the patient population seen in the pediatric gastroenterology clinics of the participating institutions. Males and females of any race between the ages of 5 and 13 years, inclusive, were considered for study entry. Thirty-two patients were enrolled in the study, 28 patients completed and four patients discontinued.

TREATMENT SUMMARY Seventeen patients received lactulose and 15 received placebo treatment. Dose was titrated by the physician depending on effect, starting with a nightly oral dose of 2 mL/kg of body weight up to a maximum of 60 mL/day. Patients completing the study received four weeks of treatment.

STUDY STATUS The study was completed.
RESULTS: PATIENT INFORMATION
Twenty-five male and 7 female children ranging in age from 4.9 to 12.6 years were enrolled in the study. The majority of children were Caucasian (68.8%) with African-American (25.0%) and Hispanic (6.2%) making up the remainder of the study population. The treatment groups were comparable at baseline with respect to sex, race, age, weight and height.

RESULTS: EFFICACY
For the primary efficacy parameters, Clinical Evaluation of Encopresis (CEE) and Clinical Global Improvement (CGI), lactulose treatment resulted in a greater improvement over baseline compared to placebo treatment at all weeks assessed. These treatment differences were statistically significant at Weeks 2 (CEE) and 2, 3 and 4 (CGI).

RESULTS: SAFETY
Lactulose was shown to be safe and well tolerated at doses up to 60 mL daily. The most commonly reported adverse events following lactulose treatment included abdominal pain, vomiting, and diarrhea which are most likely a result of the pharmacologic effects of the drug.

CONCLUSIONS
Clear trends favoring lactulose were evident in both physician- and patient-rated efficacy parameters measuring encopresis, constipation, stool retention, stool consistency and stool frequency. In addition, lactulose proved to be safe and well-tolerated at oral doses up to 60 mL daily.