

Efficacy of lansoprazole in the treatment of gastroesophageal reflux disease in children.

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Abstract

OBJECTIVES: To assess the efficacy of lansoprazole for the relief of symptoms due to gastroesophageal reflux disease (GERD) in children 1 to 11 years of age. In addition, the efficacy in healing of erosive esophagitis (EE) was determined in those children with EE who were enrolled in the study. **METHODS:** In this phase I/II, open-label, multicenter (11 sites) U.S. study, children with symptomatic GERD, EE by endoscopy, and/or intraesophageal pH < 4 for greater than 4.2% of the time based on 24-hour pH testing were assigned, on the basis of body weight, to lansoprazole 15 mg (< or = 30 kg) or 30 mg (> 30 kg) once daily for 8 to 12 weeks. At the discretion of the investigator, the dosage of lansoprazole was increased up to 60 mg daily in children who continued to be symptomatic after 2 weeks of treatment. Symptom response was assessed by investigator interview and daily diary. Esophagitis healing was evaluated by repeat endoscopy after 8 and, if applicable, 12 weeks of treatment. **RESULTS:** Sixty-six children were enrolled. At week 8, 78% (21/27) of the children with EE at baseline had healed; the remaining six children were healed by week 12 (100%, 6/6). By investigator interview, 70% of children experienced resolution or improvement in their overall symptoms of GERD by their final visit. Statistically significant reductions from baseline in the severity of each symptom were reported with the exceptions of wheezing, hematemesis, and melena. Based on daily diary data, improvement in overall GERD symptoms was reported in 76% (47/62) of all children. With few exceptions, significant ($P < 0.05$) reductions from baseline occurred during each of the 2-week treatment intervals of the study period in the percentage of days and the average daily severity of GERD symptoms, the percentage of days antacid was used, and the average number of antacid

tablets used per day. CONCLUSION: In children 1 to 11 years of age, lansoprazole is efficacious in healing EE and in relieving GERD-related symptoms.



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