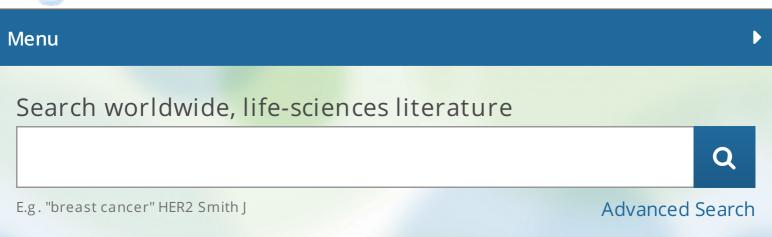
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Gremse D , Winter H , Tolia V , Gunasekaran T , Pan WJ , Karol M , Chiu YL , Pilmer B , Book L

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Type: Clinical Trial, Phase II, Clinical Trial, Research Support, Non-U.S. Gov't, Multicenter Study, Clinical Trial, Phase I, Journal Article

Abstract

OBJECTIVES: To evaluate the pharmacokinetics and pharmacodynamics of lansoprazole in children between 1 and 11 years of age with gastroesophageal reflux disease (GERD). METHODS: In a multicenter, open-label trial of pediatric patients with symptomatic GERD, children were assigned, based on their weight, to receive lansoprazole 15 mg (patients weighing < or = 30 kg) or lansoprazole 30 mg (patients weighing > 30 kg) once daily. The effects of lansoprazole on 24hour median intragastric pH, the percentages of time intragastric pH was above 3 and 4, and pharmacokinetic parameters were assessed at the day-5 visit and compared to baseline. RESULTS: Sixty-six children were enrolled in the study. Mean lansoprazole C(max) values of 790.9 ng/mL and 898.5 ng/mL and T(max) values of 1.5 hours and 1.7 hours were observed in the < or = 30 kg and the > 30 kg body weight treatment groups, respectively. AUC0-24 values of 1707 ng x h/mL and 1883 ng x h/mL and T1/2 values of 0.68 hours and 0.71 hours were observed in the < or = 30 kg and > 30 kg lansoprazole body weight treatment groups, respectively. There was no statistical significant difference in AUC0-24 between the two groups (P = 0.2571). After 5 days of treatment lansoprazole produced significant increases in patients' 24-hour mean intragastric pH and the percentages of time intragastric pH was above 3 and 4 compared to baseline. CONCLUSION: The observed pharmacokinetic properties of lansoprazole in

children between 1 and 11 years of age with GERD were similar to those previously observed in healthy adult subjects. Lansoprazole significantly increased the mean 24-hour intragastric pH and the percentages of time intragastric pH was above 3 and 4 when children were dosed with either 15 or 30 mg according to body weight.



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