

# Pharmacokinetics and pharmacodynamics of lansoprazole in children with gastroesophageal reflux disease.

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## 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  $\leq$  30 kg) or lansoprazole 30 mg (patients weighing  $>$  30 kg) once daily. The effects of lansoprazole on 24-hour 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  $\leq$  30 kg and the  $>$  30 kg body weight treatment groups, respectively. AUC<sub>0-24</sub> values of 1707 ng x h/mL and 1883 ng x h/mL and T<sub>1/2</sub> values of 0.68 hours and 0.71 hours were observed in the  $\leq$  30 kg and  $>$  30 kg lansoprazole body weight treatment groups, respectively. There was no statistical significant difference in AUC<sub>0-24</sub> 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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