

The following research describes lack of effective research on PPIs for infants:

"Food and Drug Administration approval of proton-pump inhibitors for infantile gastroesophageal reflux disease has been limited by inpatient variability in the clinical assessment of gastroesophageal reflux disease."

Earp JC, Mehrotra N, Peters KE, et al. [Esomeprazole FDA Approval in Children With GERD: Exposure-Matching and Exposure-Response](#). *J Pediatr Gastroenterol Nutr*. 2017

"Their effectiveness for treatment of peptic conditions in the pediatric population, including gastric ulcers, gastroesophageal reflux disease (GERD), and Helicobacter pylori infections has been established for children older than 1 year. Studies of the preverbal population of neonates and infants have identified doses that inhibit acid production, but the effectiveness of PPIs in the treatment of GERD has not been established except for the recent approval of esomeprazole treatment of erosive esophagitis in infants. Reasons that have been proposed for this are complex, ranging from GERD not occurring in this population to a lack of histologic identification of esophagitis related to GERD to questions about the validity of symptom scoring systems to identify esophagitis when it occurs in infants."

Ward RM, Kearns GL. [Proton pump inhibitors in pediatrics : mechanism of action, pharmacokinetics, pharmacogenetics, and pharmacodynamics](#). *Paediatr Drugs*. 2013

"The strategies that have been proposed for the pharmacological treatment of GERD in children are primarily based on studies of case series or on studies with adults. There have been very few controlled and randomized studies in children. Undertaking a greater number of these studies might reinforce existing aspects or establish new aspects of management."

Guimarães EV, Marguet C, Camargos PA. [Treatment of gastroesophageal reflux disease](#). *J Pediatr (Rio J)*. 2006

"However, the pharmacokinetics of PPIs have not been studied in children less than two years old. In general children, under 4 months had higher omeprazole levels and an immature metabolism. Studies in children older than 2 years old have showed similar pharmacokinetics to adults."

Hoyo-Vadillo C, Venturelli CR, González H, et al. [Metabolism of omeprazole after two oral doses in children 1 to 9 months old](#). *Proc West Pharmacol Soc*. 2005

"All infants, including premature infants as young as 24 weeks' gestational age, are able to maintain an intragastric pH below 4 from the first day of life. By 24 weeks, maximal acid output approaches that in adults. In adult studies, proton pump inhibitors (PPIs) are highly effective in relieving reflux symptoms and healing reflux esophagitis. Studies are needed to evaluate PPI efficacy and appropriate dosing in infants and children. Consequences such as hypergastrinemia, bacterial overgrowth, and other potential adverse events associated with long-term PPI use also warrant evaluation in the pediatric population."

Boyle JT. [Acid secretion from birth to adulthood](#). *J Pediatr Gastroenterol Nutr*. 2003