

FDA News

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FDA Approves Nexium for Use in Children Ages 1-11 Years

The U.S. Food and Drug Administration approved Nexium (esomeprazole magnesium) for short-term use in children ages 1-11 years for the treatment of gastroesophageal reflux disease (GERD). The agency approved Nexium in two forms, a delayed-release capsule and liquid form. Nexium is approved in 10 milligrams (mg) or 20 mg daily for children 1-11 years old compared to 20 mg or 40 mg recommended for pediatric patients 12 to 17 years of age.

"This approval provides important information for appropriate dosing for children ages 1-11 years with GERD," said Julie Beitz, M.D., director of the FDA's Office of Drug Evaluation III in the Center for Drug Evaluation and Research. "Children prescribed this drug should be monitored by their physicians for any adverse drug reactions."

Nexium is part of a class of drugs known as proton pump inhibitors (PPIs). PPIs decrease the amount of acid produced in the stomach and help heal erosions in the lining of the esophagus known as erosive esophagitis.

FDA approved the use of Nexium in patients 1 to 11 years for short-term treatment of GERD based upon the extrapolation of data from previous study results in adults to the pediatric population, as well as safety and pharmacokinetic studies performed in pediatric patients. In one study, 109 patients 1-11 in age, diagnosed with GERD, were treated with Nexium once-a-day for up to eight weeks to evaluate its safety and tolerability. Most of these patients demonstrated healing of their esophageal erosions after eight weeks of treatment.

The most common adverse reactions in children treated with Nexium were headache, diarrhea, abdominal pain, nausea, gas, constipation, dry mouth and sleepiness. The safety and efficacy of Nexium has not been established in children less than one year of age.

Nexium is manufactured by AstraZeneca of Wilmington, DE.