How children with obesity process pantoprazole and dosing recommendations

WHY WAS THIS STUDY NEEDED?

In the United States, 1 in 5 children have obesity. Children are considered obese when they have excess body fat that can cause a risk to their health. One condition connected to obesity is gastroesophageal reflux disease (GERD). GERD is a condition where one's stomach contents flow back up into their throat, causing discomfort. Pantoprazole is a medicine that is commonly used to treat GERD. However, obesity can change how a child processes it.

This study by the Pediatric Trials Network (PTN), called The Effect of Obesity on the Pharmacokinetics of Pantoprazole in Children and Adolescents, was needed to learn how children with obesity process pantoprazole compared to children without obesity. It was also needed to learn the safest, most effective amount of pantoprazole to give children with obesity.

WHAT WERE THE STUDY RESULTS?

After accounting for body size, researchers found that children with obesity processed pantoprazole differently from children without obesity. The weight-based dosing recommendations on the pantoprazole label performed well. A medicine's label has the necessary information for health care providers to use when prescribing it. Additionally, researchers found that variations to a certain gene can affect how children process pantoprazole.

WHAT HAPPENED NEXT?

Researchers submitted the information learned from this study to the U.S. Food and Drug Administration (FDA). In the future, this information could lead to an update to the pantoprazole label.

Future studies of pantoprazole and other similar medicines can help us learn more about how children with obesity process them.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

A summary of the results of this study, as well as related publications and news, can be found at pediatrictrials.org.

** This summary was completed in June 2026. Newer information since this summary was written may exist. This summary includes results from one PTN study. Other studies may find different results.*

WHAT KIND OF STUDY WAS THIS?

This was a pharmacokinetic study to learn how children with obesity process pantoprazole. Pharmacokinetics is the study of how our bodies process medicines. Understanding pharmacokinetics makes sure that children receive the right amounts of medicine.

The study took place at multiple sites across the United States. In total, 41 children (6–11 years old) and adolescents (12–17 years old) with obesity participated in the study.

WHAT HAPPENED DURING THIS STUDY?

Participants took pantoprazole as part of their treatment for GERD. They took an amount based on their lean body weight. Lean body weight is the total weight of a person's body minus fat tissue. Researchers tested the participants' blood to see how much pantoprazole was in their bodies and how much remained over time. They compared this information to previous data about how children without obesity process pantoprazole.

WHO PERFORMED THIS STUDY?

This study was performed by the PTN, a group of more than 100 research sites around the world that work to find the safest, most effective ways to use medicines and devices for infants and children. Children aren't just little adults. Their bodies are growing and changing, meaning that they process medicines and react to devices different from adults. The PTN makes sure doctors and families have the information they need to give children the best care.

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Making drugs safer & more effective for use in the youngest patients