Predicting and testing infant exposure to ondansetron in breast milk



WHY WAS THIS STUDY NEEDED?

Most breastfeeding women take at least one prescription medication. Some mothers worry that medicines they take might get into their breast milk and affect their baby. For most drugs, it is not known how much passes into a mother's breast milk. Because of this uncertainty, many women and their medical providers struggle with the decision to take important medications or stop breastfeeding.

This study by the Pediatric Trials Network (PTN), called Commonly used drugs during lactation and infant exposure (CUDDLE) was needed to learn how breastfeeding infants are exposed to medicine taken by breastfeeding women. Women who are breastfeeding may take ondansetron to treat nausea and vomiting. There was limited information about the safety of ondansetron exposure for breastfeeding infants.

WHAT KIND OF STUDY WAS THIS?

This was a pharmacokinetic study designed to show how mothers' and infants' bodies process ondansetron. Pharmacokinetics is the study of how our bodies process medicine. Understanding pharmacokinetics in breastfeeding women can tell us how it affects them and their infants. The study included 78 breastfeeding women taking ondansetron after giving birth, and their babies.

WHAT HAPPENED DURING THIS STUDY?

The mothers took ondansetron as prescribed by their regular doctors and continued breastfeeding. Researchers then tested the mothers' breast milk and the mothers' and infants' blood to see how much ondansetron was in their bodies and how much remained over time.

WHAT WERE THE STUDY RESULTS?

The study confirmed that ondansetron passes into breast milk, but at low levels, and that babies are exposed to about 3% of the mother's ondansetron dose. There were no adverse effects observed in infants exposed to ondansetron in the CUDDLE study.

WHAT HAPPENED NEXT?

The study helped researchers predict how drugs like ondansetron pass into breast milk. This information can apply to some of the other drugs in the CUDDLE study to predict infant exposure through breastmilk. The PTN submitted the data to the FDA, which led to an update to the ondansetron label stating that, at normal doses, it is safe to breastfeed after taking ondansetron. A drug's label contains necessary information for health care providers to use when prescribing it.

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.

The study was possible with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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

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

** 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.