



Observational Prucalopride Pregnancy & Lactation Studies

A Messaging Toolkit for
Healthcare Providers



PREGNANCY STUDY



Did your patient become pregnant while taking prucalopride?

Talk to them about MotherToBaby's observational research opportunity.

Who is MotherToBaby?

MotherToBaby is the nation's leading authority and most trusted source of evidence-based information on the safety of medications, health conditions and other exposures during pregnancy and while breastfeeding.

What should I tell my patient?

MotherToBaby is conducting a study on CIC and IBS-C and their treatments during pregnancy. This study is strictly observational, which means if you participate you will not be asked to change any part of your health care routine, including your medications. You should learn more about this study. If you would like, I can provide your contact information to MotherToBaby and they can call you at a later time to talk to you about the study. Or I can give you their contact information so you can reach out to them directly.

Prucalopride and Pregnancy

MotherToBaby is enrolling pregnant persons in a study examining chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) during pregnancy. They are enrolling both persons who have and who have not used prucalopride in a current or recent pregnancy. This study is being done as part of a post-marketing commitment with the FDA.

About the Study

- This study is strictly observational, which means participants who enroll will not be asked to change any part of their health care routine, including their medications.
- Participants complete 1-3 phone interviews during pregnancy and 1 phone interview after delivery. Participants are also asked to authorize release of obstetric, delivery, specialty provider, and pediatric medical records up to one year after delivery.
- No travel or changes to medication or other healthcare routines are required.

How to Refer Your Pregnant Patients

After you inform your patient about MotherToBaby Pregnancy Studies:

- Ask them if you can refer them to MotherToBaby to learn more about the study or for additional resources.
- If the patient says yes, call **877.311.8972**, visit [MotherToBaby.org/refer](https://www.MotherToBaby.org/refer) or email MotherToBaby@health.ucsd.edu

MotherToBaby Specialists are available Monday - Thursday 7am - 7pm PT, and Friday 7am-6pm PT

LACTATION STUDY



• Mommy's Milk •
HUMAN MILK RESEARCH BIOREPOSITORY

Is your breastfeeding patient taking prucalopride?

Talk to them about Mommy's Milk's observational research opportunity.

Who is Mommy's Milk?

Mommy's Milk is the nation's first research-dedicated biorepository of human milk samples. One of our goals is to better understand medication safety in lactation. Mommy's Milk is a research program housed in the Center for Better Beginnings at the University of California San Diego, Department of Pediatrics.

What should I tell my patient?

Mommy's Milk is conducting a study on prucalopride use while breastfeeding. This study is strictly observational, which means if you participate you will not be asked to change any part of your health care routine, including your medications. You should learn more about this study. If you would like, I can provide your contact information to Mommy's Milk and they can call you at a later time to talk to you about the study. Or I can give you their contact information so you can reach out to them directly.

Prucalopride and Lactation

Mommy's Milk is enrolling lactating persons in a study examining the use of prucalopride for the treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C) while breastfeeding. This study is being done as part of a post-marketing commitment with the FDA.

About the Study

- This study is strictly observational, which means participants who enroll will not be asked to change any part of their health care routine, including their medications.
- Participants can expect:
 - Phone interviews
 - Providing 4-7 milk samples over a 24-hour period before & after taking a dose of prucalopride. Samples collected at home and shipped using study-provided materials.
 - Releasing baby's medical records.
- No travel or changes to medication or other healthcare routines are required.

How to Refer Your Lactating Patients

After you inform your patient about the Mommy's Milk Prucalopride Study:

- Ask them if you can refer them to Mommy's Milk to learn more about the study.
- If the patient says yes, call 858.246.1713, visit MommysMilkResearch.org/refer or email MilkStudy@health.ucsd.edu