A Study of Prucalopride in Breastfeeding Women With Constipation

NCT04838522

Status	RECRUITING
Sponsor	Takeda
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (7)

- Female participants with an ability to voluntarily provide verbal followed by written, signed, and dated (personally or via a legally authorized representative) informed consent as applicable to participate in the study.
- Participants greater than or equal to (\>=) 18 years of age at the time of consent. This inclusion criterion will only be assessed at the time of enrollment.
- Participants who are currently breastfeeding a singleton infant who is between 10 days and 11 months 0 days, inclusive. Note that participants pumping breast milk and bottle feeding their infant breast milk are allowed to participate.
- Participants who are currently exclusively breastfeeding or breastfeeding with supplemental formula and/or solid food. Infants who are exclusively breastfed and do not yet eat solid food are preferred.
- Participants who are currently treated as prescribed by their physician with MOTEGRITY or RESOTRAN (generic forms of prucalopride not allowed) for functional constipation, including chronic idiopathic constipation (CIC) and irritable bowel syndrome-constipation (IBS-C), for at least 5 consecutive days at the time of taking the first breastmilk sample.

... and 2 more (see full listing online)

Exclusion (5)

- Participants who are breastfeeding an infant who: is hospitalized, has a major birth defect, or has a history of a disease that could affect absorption or drug disposition.
- Participants who have used MOTEGRITY or RESOTRAN while breastfeeding for a condition other than functional constipation.
- Participants who are pregnant at the time of enrollment.
- Participants who have started to wean their child from breast milk.
- Participants with a history of any hematological, hepatic, respiratory, cardiovascular, renal, gall bladder removal, or other current or recurrent disease that could affect the action, absorption, or disposition of prucalopride.

Locations (1 total)

University of California San Diego, La Jolla, California, United States

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