

# TAK-555-5001: Prucalopride Pregnancy Exposure Study: A VAMPSS Post-Marketing Surveillance of Prucalopride Safety in Pregnancy

**First published:** 16/04/2021

**Last updated:** 11/08/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS40231

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### Study ID

48262

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

This study collects information on pregnant women with ongoing constipation who took prucalopride and those who did not take prucalopride. The main aim of the study is to learn if any medical problems in pregnant women or their infants might be related to taking prucalopride during their pregnancy.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

#### Organization of Teratology Information Specialists (OTIS)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### **Study institution contact**

Study contact [Takeda TrialDisclosures@takeda.com](mailto:TakedaTrialDisclosures@takeda.com)

**Study contact**

[TrialDisclosures@takeda.com](mailto:TrialDisclosures@takeda.com)

### **Primary lead investigator**

# Study contact Takeda

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/06/2019

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### Study start date

Actual: 21/05/2021

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### Data analysis start date

Planned: 01/03/2027

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### Date of final study report

Planned: 01/10/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda

## Study protocol

[TAK-555-5001 Protocol V4.0\\_redacted.pdf](#) (1.54 MB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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## Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

## Other study registration identification numbers and links

[ClinicalTrials.gov: NCT04869280](https://clinicaltrials.gov/ct2/show/study/NCT04869280)

[Study information](#)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

The objective is to evaluate the potential effect of exposure to prucalopride in pregnancy compared with a group of disease-matched pregnant women who are not exposed to prucalopride.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Study drug International non-proprietary name (INN) or common name**

PRUCALOPRIDE

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### **Anatomical Therapeutic Chemical (ATC) code**

(A06AX05) prucalopride

prucalopride

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### **Medical condition to be studied**

Constipation

## Population studied

### **Age groups**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

616

## Study design details

### **Outcomes**

Major Structural Defects in Children:

1. Number of Participants With Spontaneous Abortion/Miscarriage
  2. Number of Participants With Stillbirth
  3. Number of Participants With Elective Termination/Abortion
  4. Number of Participants With Premature Delivery
  5. Small for Gestational Age
  6. Postnatal Growth Deficiency of Live Born Children
  7. Screening for Neurodevelopmental Milestones
  8. Hospitalization in Live Born Children
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### **Data analysis plan**

Major structural defects in children will be analyzed.

The primary comparison will be the birth prevalence of major structural defects between exposed group and unexposed group among pregnancies resulting in at least one live born infant.

## Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

Other

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### Data sources (types), other

Prospective patient-based data collection, Exposure registry

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No