

PATIENT INFORMATION
Prucalopride (proo-kal-oh-pride)
Prucalopride tablets, for oral use

What are Prucalopride Tablets?

Prucalopride tablets are prescription medicine used in adults to treat a type of constipation called chronic idiopathic constipation (CIC). Idiopathic means the cause of the constipation is unknown.

It is not known if Prucalopride tablets is safe and effective in children.

Do not take Prucalopride tablets if you:

- are allergic to prucalopride. Allergic reaction symptoms may include trouble breathing, rash, itching and swelling of your face, lips, tongue or throat.
- have a tear in your stomach or intestinal wall (bowel perforation), a bowel blockage (intestinal obstruction) or serious conditions of the intestinal wall such as Crohn's disease or ulcerative colitis.

Before taking Prucalopride tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had depression, suicidal thoughts or actions, or mood problems.
- have kidney problems. Your healthcare provider may give you a lower dose of prucalopride tablets.
- are pregnant or plan to become pregnant. It is not known if prucalopride will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Prucalopride can pass into your breastmilk. Talk with your healthcare provider about the best way to feed your baby if you take prucalopride tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take Prucalopride Tablets?

- Take 1 prucalopride tablet each day or as directed by your healthcare provider.
- Take prucalopride tablets exactly as your healthcare provider tells you to take it.
- Take prucalopride tablets with or without food.

What are the possible side effects of Prucalopride Tablets?

Prucalopride tablets may cause serious side effects, including:

unusual changes in mood or behavior, thoughts of hurting yourself, trying to hurt yourself, or suicide. Stop taking Prucalopride tablets right away and tell your healthcare provider immediately if your depression gets worse, you feel sad, hopeless, begin to have thoughts of suicide, thoughts of hurting yourself or you have tried to hurt yourself or if you develop new depression.

The most common side effects of prucalopride tablets include:

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| • headache | • nausea | • dizziness | • gas |
| • stomach area (abdominal) pain or bloating | • diarrhea | • vomiting | • fatigue |

These are not all the possible side effects of prucalopride tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Prucalopride Tablets?

- Store Prucalopride tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store Prucalopride tablets in the original container to protect from moisture.

Keep Prucalopride tablets and all medicines out of the reach of children.

General information about the safe and effective use of Prucalopride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use prucalopride tablets for a condition for which it was not prescribed. Do not give prucalopride tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about prucalopride tablets that is written for health professionals.

What are the ingredients in Prucalopride Tablets?

Active ingredient: prucalopride

Inactive ingredients: lactose monohydrate, magnesium stearate, and microcrystalline cellulose and silica, colloidal anhydrous. The coating for 1 mg tablet contains hypromellose, iron oxide yellow, lactose monohydrate, talc titanium dioxide, and triacetin. The coating for 2 mg tablet contains hypromellose, lactose monohydrate, titanium dioxide and triacetin.



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Manufactured for:

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This Patient Information has been approved by the U.S. Food and Drug Administration

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