

# Prupair 2 Tablet

**Product Information: Prucalopride (2 mg)  
Injection**

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**constipation, when oral formulations are  
not suitable.**

## Composition

- **Prucalopride: 2 mg per injection  
(injection solution).**
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**It is typically used when oral therapy is not an  
option or when faster action is required.**

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## Pharmacological Class

- **Class: Selective serotonin (5-HT<sub>4</sub>)  
receptor agonist.**
  - **Mechanism of Action: Prucalopride is a  
selective agonist at the 5-HT<sub>4</sub> receptor in  
the gastrointestinal tract. By stimulating  
these receptors, it enhances the motility  
of the intestines and accelerates  
peristalsis (the coordinated muscle  
contractions that move food through the  
digestive tract). This effect is useful in  
patients with chronic constipation, as it  
improves bowel movements and relieves  
symptoms.**
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## Dosage and Administration

- **Adults:**
  - **The recommended dose of  
Prucalopride 2 mg injection is 2  
mg once daily via subcutaneous  
injection, preferably at the same  
time each day.**
  - **The injection should be  
administered under the skin  
(subcutaneously) of the thigh or  
abdomen.**
  - **Treatment should be reassessed  
after 4 weeks of therapy to  
evaluate effectiveness and the need  
for continued use.**
- **Elderly:**
  - **In elderly patients (above 65  
years), the dose should generally  
be started at 1 mg per day,  
increasing to 2 mg if well-  
tolerated.**
- **Renal Impairment:**
  - **Severe renal impairment (eGFR <  
30 mL/min): Prucalopride is not  
recommended in patients with  
severe renal impairment unless  
closely monitored by a healthcare  
provider. A dose adjustment may  
be necessary.**
  - **Mild to moderate renal  
impairment: No dose adjustment  
is required.**
- **Hepatic Impairment:**

## Indications

**Prucalopride (2 mg) injection is primarily  
indicated for the short-term treatment of:**

1. **Chronic Idiopathic Constipation: In  
adults who have not responded to other  
laxatives or in patients who cannot take  
oral medication.**
2. **Functional Constipation: Management  
of chronic constipation when other  
treatments are ineffective.**
3. **Constipation Associated with Other  
Conditions: Such as opioid-induced**

- **Mild to moderate hepatic impairment: No dose adjustment is needed.**
- **Severe hepatic impairment: Caution should be exercised, and dose adjustments may be required.**
- **Pediatric Use:**
  - **The use of Prucalopride injection in children is not recommended due to insufficient clinical data on safety and efficacy.**

- **Prucalopride should be used with caution in patients with a history of gastrointestinal perforation or intestinal obstruction.**

### **3. Electrolyte Imbalances:**

- **Caution is needed in patients with electrolyte imbalances (especially hypokalemia), as these can exacerbate adverse effects.**

### **4. Renal and Hepatic Impairment:**

- **Monitor closely for side effects in patients with severe kidney or liver dysfunction.**

### **5. Psychiatric Effects:**

- **Prucalopride has been associated with mood changes, including depression, in rare cases. It should be used cautiously in patients with a history of depression.**

### **6. Pregnancy and Breastfeeding:**

- **Pregnancy: Prucalopride should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.**
- **Breastfeeding: Prucalopride is excreted in human milk, so it should be used with caution in breastfeeding women.**

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## **Contraindications**

- **Hypersensitivity: Known allergy or hypersensitivity to Prucalopride or any of the excipients in the injection.**
- **Severe Renal Impairment (eGFR < 30 mL/min): Due to limited data, the use of Prucalopride in patients with severe kidney dysfunction is contraindicated.**
- **Gastrointestinal Obstruction or Perforation: Prucalopride should not be used in patients with intestinal obstruction, perforation, or inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis).**
- **Severe Cardiovascular Disorders: Caution is advised in patients with significant heart conditions (e.g., ischemic heart disease, arrhythmias).**

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## **Adverse Effects**

- **Common:**
  - **Diarrhea, headache, abdominal discomfort, nausea, and bloating.**
- **Serious:**
  - **Gastrointestinal perforation, severe abdominal pain, or distention.**
  - **Electrolyte imbalances: Low potassium levels (hypokalemia).**
  - **Cardiovascular events: Arrhythmias, including palpitations, tachycardia, or QT prolongation.**

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## **Warnings and Precautions**

- 1. Cardiovascular Effects:**
  - **Prucalopride may prolong the QT interval on the electrocardiogram (ECG), which could increase the risk of arrhythmias. It should be used cautiously in patients with known cardiac arrhythmias or other cardiovascular issues.**
- 2. Gastrointestinal Adverse Effects:**

- **Mood disturbances: Depression, anxiety, and other psychiatric symptoms.**
  - **Less Common:**
    - **Rash, itching, or signs of hypersensitivity reactions.**
    - **Dizziness or lightheadedness upon standing.**
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### Drug Interactions

- **QT-prolonging Drugs: Prucalopride should be used with caution if taken alongside drugs that prolong the QT interval (e.g., antiarrhythmics, certain antidepressants).**
  - **CYP3A4 Inhibitors: While Prucalopride is not significantly metabolized by CYP enzymes, drugs that affect gastrointestinal motility may alter its effectiveness.**
  - **Laxatives: When used with other laxatives, close monitoring is recommended to prevent excessive bowel stimulation.**
  - **Digoxin: Prucalopride may increase the serum concentration of digoxin, so dosage adjustments should be considered.**
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### Storage Instructions

- **Store at room temperature (15°C to 30°C), away from moisture and direct heat.**
  - **Do not freeze.**
  - **Keep the injection in its original packaging until use to protect from light.**
  - **Keep out of reach of children.**
  - **Do not use beyond the expiration date on the packaging.**
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### Clinical Benefits

- **Effective in managing constipation: Prucalopride provides quick and effective relief for patients with chronic idiopathic constipation who cannot tolerate oral treatments.**
  - **Convenient delivery: The injection is ideal for patients who cannot take oral medications or require rapid relief.**
  - **Targeted action: It acts specifically on the 5-HT<sub>4</sub> receptors, enhancing gastrointestinal motility and improving symptoms related to constipation without systemic side effects.**
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### Packaging

- **Prucalopride 2 mg injection is available in pre-filled syringes or vials containing 2 mg per 1 ml of solution. The injection comes in a pack of 1, 5, or 10 syringes/vials, depending on the manufacturer.**
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**Prucalopride (2 mg) Injection is a highly effective treatment option for chronic constipation, providing rapid relief through subcutaneous administration. It is especially useful for patients who cannot take oral medications or need faster results, with minimal side effects when used according to recommended guidelines.**

Manufactured in India for:

**Cafoli**<sup>TM</sup>  
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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