

Prupair 2 Tablet

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

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

**It is typically used when oral therapy is not an
option or when faster action is required.**

Composition

- **Prucalopride: 2 mg per injection
(injection solution).**

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:**

Pharmacological Class

- **Class: Selective serotonin (5-HT₄) receptor agonist.**
- **Mechanism of Action: Prucalopride is a selective agonist at the 5-HT₄ 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.**

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.
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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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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:**

- 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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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.

- **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-HT₄ 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:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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