

Prupair 1 Tablet

Product Information: Prucalopride (1 mg) Tablet

bowel syndrome (IBS) with constipation or opioid-induced constipation.

Composition

- **Prucalopride: 1 mg per tablet.**

Pharmacological Class

- **Class: Selective serotonin (5-HT₄) receptor agonist.**
- **Mechanism of Action: Prucalopride is a selective agonist of the 5-HT₄ receptor in the gastrointestinal tract. By stimulating these receptors, Prucalopride enhances peristalsis (the wave-like muscle contractions in the intestines), increasing motility and improving bowel movement. This action helps alleviate constipation, particularly in patients with chronic constipation.**

Indications

Prucalopride (1 mg) tablet is primarily used for the treatment of:

1. **Chronic Idiopathic Constipation: Management of constipation in adults who have not responded adequately to other laxatives or have no clear underlying cause for their constipation.**
2. **Functional Constipation: Can be used when other treatments have failed or are not suitable.**
3. **Chronic Constipation Associated with Other Conditions: Such as irritable**

Dosage and Administration

- **Adults:**
 - **Standard Dosage: 1 tablet of Prucalopride 1 mg once daily, preferably taken at the same time each day, with or without food.**
 - **If there is no sufficient response after 4 weeks, the treatment may be reassessed.**
 - **Maximum Dose: 2 mg per day if clinically required (based on individual patient response).**
 - **If treatment is discontinued for a period of time and then resumed, the starting dose should be 1 mg once daily.**
- **Elderly (over 65 years):**
 - **Start with 1 mg daily. If necessary, the dose may be increased to 2 mg daily, but elderly patients may be more susceptible to adverse effects. Close monitoring is recommended.**
- **Renal Impairment:**
 - **Mild to moderate renal impairment: No dose adjustment is needed.**
 - **Severe renal impairment (eGFR < 30 mL/min): Use with caution, and the maximum recommended dose is 1 mg per day.**
- **Hepatic Impairment:**
 - **Mild to moderate hepatic impairment: No dose adjustment is needed.**
 - **Severe hepatic impairment: Caution should be exercised, and**

dose adjustments may be necessary.

- **Pediatric Use:**
 - Prucalopride is not recommended for children below 18 years of age due to lack of sufficient safety and efficacy data.

- **Pregnancy:** Prucalopride should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- **Breastfeeding:** Prucalopride is excreted in breast milk, and caution is advised when administered to breastfeeding women.

Contraindications

- Hypersensitivity to Prucalopride or any of the tablet's excipients.
- Severe renal impairment (eGFR < 30 mL/min) unless recommended by a physician.
- Intestinal perforation, intestinal obstruction, or severe inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis).
- History of severe cardiovascular conditions (e.g., ischemic heart disease, arrhythmia) should use caution or avoid use of Prucalopride.

- 5. **Gastrointestinal Issues:** If symptoms like abdominal pain, bloating, or cramping occur, treatment should be reassessed.
- 6. **Risk of Dependency:** Long-term use of Prucalopride should be monitored to avoid potential overuse or dependency on the medication.

Warnings and Precautions

1. **Cardiovascular Conditions:** Prucalopride may have cardiovascular effects such as QT prolongation, especially at higher doses. It should be used cautiously in patients with heart disease, arrhythmias, or those on other medications that prolong the QT interval.
2. **Electrolyte Imbalance:** Caution is advised in patients with an electrolyte imbalance, particularly hypokalemia or hyponatremia.
3. **Renal Function:** Patients with severe renal impairment should use Prucalopride with caution, and the dose should not exceed 1 mg per day.
4. **Pregnancy and Breastfeeding:**

Adverse Effects

- **Common:**
 - Diarrhea, headache, nausea, abdominal discomfort, bloating, dizziness.
- **Serious:**
 - Severe gastrointestinal issues such as gastrointestinal perforation, intestinal obstruction.
 - Cardiovascular events such as arrhythmia or palpitations (due to QT prolongation).
 - Hypokalemia and other electrolyte imbalances.
 - Hypersensitivity reactions: Rash, itching, swelling, or severe allergic reactions (anaphylaxis).
 - Mood changes: In rare cases, mood disturbances, including depression, have been reported.

Drug Interactions

- **QT-prolonging drugs:** Caution is recommended when using Prucalopride

with other drugs that prolong the QT interval (e.g., antiarrhythmics, antipsychotics).

- **Cytochrome P450 inhibitors:** Prucalopride is not significantly metabolized by CYP enzymes, but caution should be used with drugs that may alter motility or affect gut transit time.
- **Other Laxatives:** Prucalopride should not be used concurrently with other stimulant laxatives without medical supervision.
- **Digoxin:** Use with caution as prucalopride may increase the serum concentration of digoxin.

Storage Instructions

- Store at room temperature (15°C to 30°C), in a dry place.
- Keep the tablets in their original blister packaging to protect from moisture.
- Keep out of reach of children.
- Do not use beyond the expiration date.

Clinical Benefits

- **Effective treatment for chronic constipation:** Prucalopride is specifically indicated for chronic idiopathic constipation in patients who have not responded to other therapies, improving stool frequency and consistency.
- **Improved bowel motility:** Prucalopride is beneficial for enhancing gastrointestinal motility and improving symptoms of constipation-related discomfort.
- **Well-tolerated:** Generally well tolerated with a low incidence of side effects, particularly when used at the recommended doses.

Packaging

- Prucalopride (1 mg) tablets are available in blister packs or bottles containing 7, 14, 28, or 30 tablets, depending on the manufacturer.

Prucalopride (1 mg) Tablet is a well-established treatment for chronic constipation, particularly for patients who have not found relief with other laxatives. It works by promoting bowel motility and is generally well tolerated with minimal side effects when used appropriately.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

TM: Trademark Applied for