Prucalax

(Prucalopride)

1mg & 2mg Film Coated Tablets

پرُوکالیکس

(پرُوکالوپرائڈ)

۱ ملی گرام اور ۲ ملی گرام گولیاں

COMPOSITION

Prucalax 1mg

Each film coated tablet contains:
Prucalopride (as Succinate) ..... 1 mg

Prucalax 2mg

Each film coated tablet contains:
Prucalopride (as Succinate) ..... 2 mg

DESCRIPTION

Prucalopride tablets for oral use contain Prucalopride succinate, a dihydrobenzofurancarboxamide that is a serotonin type 4 (5-HT4) receptor agonist. The IUPAC name is: 4-amino-5-chloro-N-[1-(3-methoxypropyl)piperidin-4-yl]-2,3-dihydrobenzofuran-7-carboxamide succinate.The molecular formula is C18H26ClN3O3.C4H6O4 and the molecular weight is 485.96.

MECHANISM OF ACTION

Prucalopride, a selective serotonin type 4 (5-HT4) receptor agonist, is a gastrointestinal (GI) prokinetic agent that stimulates colonic peristalsis (high-amplitude propagating contractions [HAPCs]), which increases bowel motility.

INDICATIONS AND USAGE

Prucalax is a serotonin-4 (5-HT4) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

DOSAGE AND ADMINISTRATION

- Take with or without food.
- Recommended dosage is as following:

Population with CIC	Recommended Oral Dose Regimen
Adults	2 mg once daily
Patients with severe renal impairment (creatinine clearance (CrCL) less than 30 mL/min.	1 mg once daily

CONTRAINDICATIONS

- Hypersensitivity to Prucalopride.
- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum.

WARNINGS AND PRECAUTIONS

Before taking Prucalax, tell your healthcare provider about all of your medical conditions, including if you:
- are allergic to Prucalopride.
- 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.
- have or have had depression, suicidal thoughts or actions, or mood problems.
- have kidney problems. Your healthcare provider may give you a lower dose.
- are pregnant or plan to become pregnant. It is not known if Prucalax 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 Prucalax. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

DRUG INTERACTIONS

Prucalopride shows drug interation with following drugs warfarin, digoxin, paroxetine, or oral contraceptives (ethinyl estradiol and norethisterone), Ketoconazole.

ADVERSE REACTIONS

Prucalax may cause serious side effects, including:
- unusual changes in mood or behavior, thoughts of hurting yourself, trying to hurt yourself, or suicide. Stop taking Prucalax right away and tell your healthcare provider immediately if your depression gets worse, you feel sad, hopeless or begin to have thoughts of suicide, thoughts of hurting yourself or have tried to hurt yourself.

The most common side effects of Prucalax include:
- Headache, nausea, dizziness, gas, stomach area (abdominal) pain or bloating, diarrhea, vomiting, fatigue.

PREGNANCY & LACTATION

Prucalax uses in pregnant women are insufficient to identify any drug-associated risks of miscarriage, major birth defects, or adverse maternal or fetal outcomes.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Prucalax and any potential adverse effects on the breastfed child from Prucalax or from the underlying maternal condition.

PEDIATRIC & GERIATRIC USE

The safety and effectiveness of Prucalax have not been established in pediatric patients.
No overall differences in safety and effectiveness were observed between elderly and younger patients.

OVERDOSAGE

An overdose may result in appearance of symptoms like headache, nausea, and diarrhea. Specific treatment is not available for Prucalax overdose. Treat symptomatically and institute supportive measures, as required. Extensive fluid loss from diarrhea or vomiting may require correction of electrolyte disturbances.

STORAGE CONDITIONS AND INSTRUCTIONS

- Store below 30°C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

PRESENTATION

Prucalax 1mg tablet is available in blister pack of 10's.
Prucalax 2mg tablet is available in blister pack of 10's.

ہدایات:

- **خوراک** ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

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