

PART III: CONSUMER INFORMATION

Pr[®]RESOTRAN[®]

Prucalopride tablets
(as prucalopride succinate)

This leaflet is a summary and will not tell you everything about RESOTRAN[®]. Contact your doctor or pharmacist if you have any questions about the drug. This leaflet is Part III of a three-part "Product Monograph" published when RESOTRAN[®] was approved for sale in Canada and is designed specifically for Consumers.

ABOUT THIS MEDICATION

What the medication is used for:

Treatment of chronic constipation in adult females when laxatives do not provide adequate relief.

What it does:

RESOTRAN[®] increases the frequency of bowel movements to provide a feeling of complete evacuation by stimulating peristalsis, the muscular contractions of the gut needed for bowel movements.

When it should not be used:

- If you are allergic to any of the ingredients in RESOTRAN[®] (see **What the nonmedicinal ingredients are**)
- If you need dialysis
- If you have serious problems with your gut like blockages, holes in your intestine, Crohn's disease or ulcerative colitis

RESOTRAN[®] is not recommended in children younger than 18 years old.

What the medicinal ingredient is:

Prucalopride succinate

What the nonmedicinal ingredients are:

1 mg prucalopride tablets:
colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, macrogol 3000, titanium dioxide, triacetin

2 mg prucalopride tablets:
colloidal silicon dioxide, FD&C blue #2 aluminum lake, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, macrogol 3000, titanium dioxide, triacetin

What dosage forms it comes in:

Tablets, 1 mg and 2 mg prucalopride, as prucalopride succinate

WARNINGS AND PRECAUTIONS

BEFORE you use RESOTRAN[®] talk to your doctor or pharmacist if:

- You have any diseases affecting the liver, kidney, and/or lung;
- You have any neurological problems (these affect your nervous system) or suffer from psychiatric problems;
- You have cancer, AIDS or endocrine disorders;
- You have a history of abnormal heartbeat (arrhythmia) or heart disease;
- You have insulin-dependent diabetes;
- You are using oral contraceptives for birth control; If you develop severe diarrhea, oral contraceptives may lose effectiveness and an additional method of contraception is recommended. Cases of unintended pregnancies have been reported for RESOTRAN[®];
- If you have a rare hereditary problem of galactose intolerance, Lapp deficiency or glucose/galactose malabsorption, then you should not use RESOTRAN[®] as it contains lactose;
- You are required to drive and use machines or other equipment;
- You are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed. Prucalopride is excreted in human breast milk.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with RESOTRAN[®] include: ketoconazole, and erythromycin. Atropine-like substances may reduce the effect of RESOTRAN[®].

PROPER USE OF THIS MEDICATION

Usual dose:

Adults (18 years of age and older): 2 mg once daily

Elderly (over 65 years of age): 1 mg once daily. Your doctor may increase the dose to 2 mg once daily if needed.

Patients with severe kidney impairment: 1 mg once daily.

Patients with severe liver impairment: 1 mg once daily. Your doctor may increase the dose to 2 mg once daily if needed.

Do not exceed a dosage of 2 mg per day. This will not add to the relief of constipation.

If there is no bowel movement in 3-4 days, contact your doctor. Your doctor may recommend an additional appropriate medication (e.g., laxative) for relief of immediate, acute constipation, at the same time as ongoing RESOTRAN[®] treatment.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

Do not double your dose. Take your regular dose when you remember.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, RESOTRAN® can cause side effects, although not everybody gets them. Please do not be alarmed by this list of side effects, you may not experience any of them.

The most common side effects include headache, stomach pain, nausea, and diarrhea. These usually occur on the first day of treatment, and then go away within a day or so. Other common side effects include passing gas, enlargement of the abdomen or stomach, upset stomach, dizziness, tiredness, back pain, sinusitis, and kidney and urinary disorders.

Uncommon side effects include migraine and spinning sensation (vertigo)

Most of these side effects are mild to moderate in intensity. If you suffer dizziness or tiredness, use caution in driving or operating machinery. In case of persistent, severe or bloody diarrhea, anal bleeding, or worsening abdominal symptoms, discontinue RESOTRAN® and consult your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Severe, persistent or bloody diarrhea or worsening abdominal symptoms (pain)			✓
Uncommon	Strong or irregular or racing heartbeat		✓	
	Chest pain		✓	
Very Rare	Unusual changes in mood or behavior; Worsening depression, feeling sad or hopeless; Suicidal thoughts or actions about hurting or killing yourself.			✓

This is not a complete list of side effects. For any unexpected effects while taking RESOTRAN®, contact your doctor or pharmacist.

HOW TO STORE IT

RESOTRAN® should be kept out of the reach and sight of children. Store between 15- 30°C. Protect from moisture.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.janssen.com/canada>
or by contacting the sponsor, Janssen Inc., at:
1-800-567-3331 or 1-800-387-8781

This leaflet was prepared by
Janssen Inc.
Toronto, Ontario M3C 1L9

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