

**PART III: CONSUMER INFORMATION****Relaxa™****Polyethylene Glycol 3350  
Powder for Oral Solution**

**This leaflet is part III of a three-part "Prescribing information" published when Relaxa™ was approved for sale in Canada and is designed specifically for Consumers.**

**This leaflet is a summary and will not tell you everything about Relaxa™. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION****What the medication is used for:**

**Relaxa™** is a laxative used to treat occasional constipation.

Lifestyle changes may help produce more regular bowel movements:

- Eat a well-balanced diet that includes fibre-rich foods, such as unprocessed bran, whole grain bread and fresh fruits and vegetables.
- Drink plenty of fluids and exercise regularly.

**What it does:**

**Relaxa™** works by holding water in the stool to soften the stool and increases the number of bowel movements. It is in a class of medications called osmotic laxatives.

**When it should not be used:**

Do not use **Relaxa™**:

- if you are allergic to polyethylene glycol.
- if you have a known or suspected bowel obstruction.
- in children under 18 years of age unless recommended by a physician.
- if you are pregnant or breastfeeding unless clearly needed and recommended by a physician.

**What the medicinal ingredient is:**

Polyethylene glycol 3350.

**What the important non-medicinal ingredients are:**

There are no non-medicinal ingredients.

**What dosage forms it comes in:**

**Relaxa™** is available as a powder form for oral administration after dissolution in water, juice, soda, coffee, tea, or any other non-alcoholic beverage.

**Relaxa™** is available in two package sizes, 238g and 510g. The dosing scoop included with each bottle is pre-measured for a single dose of 17 grams when filled to the rim.

**WARNINGS AND PRECAUTIONS**

**BEFORE you use Relaxa™ talk to your healthcare professional:**

- If you have or have ever had a bowel obstruction (blockage in the intestine) and if you have symptoms suggestive of bowel obstruction, appendicitis, or inflamed bowel (fever, nausea, vomiting, abdominal pain or bloating).
- If you have any kidney problems.
- If you are allergic to polyethylene glycol or any other medications, food, etc.
- About your medical conditions and medications.
- If you are pregnant or thinking about becoming pregnant, or if you are breast feeding.

Consult a physician immediately if your condition persists or worsens.

Should unusual cramps, bloating or diarrhea occur when taking **Relaxa™** consult a physician.

If you are elderly, stop use and contact a physician immediately if you experience diarrhea.

Overuse or extended use may cause dependence for bowel function. Do not take a larger dose of **Relaxa™**, take it more often, or take it for a longer period of time than your physician tells you to.

**INTERACTIONS WITH THIS MEDICATION**

No specific drug interactions have been demonstrated. However, the desired effect of other medications may be reduced if taken with laxatives. Avoid taking **Relaxa™** within two (2) hours of taking another medication.

Tell your physician and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking.

**PROPER USE OF THIS MEDICATION****Usual Adult Dose:**

17g of **Relaxa™** powder once per day or as directed by your physician or healthcare provider.

**Direction on how to use Relaxa™:**

- Use the measuring scoop provided to measure a single dose (17 grams) of powder.
- Pour the measured powder (17 grams) into a cup containing 8 ounces (250 mL) of water, juice, soda,

- coffee, tea or any other non-alcoholic beverage.
- Stir until completely dissolved and then drink the solution.

It may take 2 to 4 days (48 to 96 hours) for **Relaxa™** to produce a bowel movement.

You may discontinue taking the drug after you have had several satisfactory bowel movements.

**Relaxa™** should be used for one week or as directed by a physician.

**Overdose:**

There have been no reports of accidental overdose. In the event of an overdose, dehydration (with symptoms such as thirst, dry mouth, dry eyes not making tears, no perspiration, etc.) due to diarrhea may result. In the case of accidental overdose, stop taking **Relaxa™**, drink plenty of water and contact a physician or a poison control centre.

**Missed Dose:**

If you miss a dose, take the next dose as normal on the next day. Never take a double dose of **Relaxa™** to make up for a missed dose.

**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 seek urgent medical attention
		Only if severe	In all cases	
Rare	Allergic reaction (with symptoms such as hives, itching, swelling of the lips, face tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes)			√

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

**Relaxa™** may cause side effects. Tell a physician if any of these symptoms are severe or do not go away:

- Nausea
- Bloating
- Cramping
- Gas
- Diarrhea

*This is not a complete list of side effects. For any unexpected effects while taking Relaxa™ contact your doctor or pharmacist.*

**HOW TO STORE IT**

Store in a dry place at room temperature at 15° - 30°C (59° - 86°F).

Keep the container tightly closed. Keep out of reach of children.

**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 seek urgent medical attention
		Only if severe	In all cases	
Common	Nausea, abdominal bloating, cramping, and flatulence.	√		
Uncommon	Diarrhea	√		

**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:

1. Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
2. Call toll-free at 1-866-234-2345
3. 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 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*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:  
[www.relaxa.ca](http://www.relaxa.ca)  
or by contacting the sponsor, Red Leaf Medical Inc. at:  
1-877-563-7422.

This leaflet was prepared by Red Leaf Medical Inc.

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