### RI MUCIL - psyllium dietary fiber supplement granule, for solution Rij Pharmaceutical Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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### **Drug Facts**

# Active Ingredients (in each TEASPOON=7 gms)

Psyllium Hydrophilic Mucilloid 3.4 gms (approximately)

### Purpose

Fiber laxative / Dietary Fiber Supplement

### Uses

#### Fiber laxative

- effective in treating occasional constipation and restoring and maintaining regularity. Generally produces bowel movement in 12-72 hours
- encouragement for normal elimination naturally, without chemical stimulants

### **Dietary Fiber Supplement**

• Diets low in saturated fat and cholesterol that includes 7 gms of soluble fiber per day from psyllium husk, as in this product, may reduce the risk of heart disease by lowering cholesterol. One Adult dose of this product has 2.4 gms of this soluble fiber.

### Warnings

### Choking

• Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting or difficulty in swallowing or breathing after taking this product, seek immediate medical attention

### Allergy alert

• Inhaled or ingested psyllium powder may cause allergic reaction in people sensitive to psyllium

### Ask a doctor before use if

#### Laxative

- if you have a sudden change in bowel habits that persist over a period of 2 weeks
- if you have abdominal pain, nausea, or vomiting

#### **Dietary Fiber Therapy**

• you are considering use of this product as part of cholesterol-lowering program.

### When using this product

• do not use more than 7 days unless directed by a doctor

### Stop use and ask a doctor if

• you experince rectal bleeding

- you faile to have bowel movement
- constipation persists beyond 7 days, as it may be a sign of a more serious consition.

## Keep out of reach of children

In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

### Directions

Mix this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product with enough liquid may cause choking. Do not take if you have difficulty in swallowing. See choking warnings

	LAXATIVE USE	DIETARY SUPPLEMENT FIBER USE
years &	8 8 F I	1 rounded teaspoon (7 gms) in 8 oz. of liquid 3 times daily.
5	1/2 the adult dose in 8 oz. of liquid, up to 3 times daily	consult a doctor
Children under 6 years	consult a doctor	consult a doctor

- 1. Put rounded teaspoon (7 gms) in 8 oz. of liquid at the first sign of irregularity.
- 2. Fill an 8 oz. container with cold water, juice or other liquid.
- 3. Sprinkle one rounded teaspoondul (7 gms) of powder into liquid.
- 4. Stir briskly and drink immediately. If mixture thickens, add more liquid and stir. An additional glass of liquid is recommended.

### Usage Tips:

Laxatives, including bulk fibers, may affect how well other medicines work. If you are taking a prescription medicine by mouth, take this product at least 2 hours before or 2 hours after the prescribed medicine. As your boday adjusts to increase fiber intake, you may experience changes in bowel habits or minor bloating.

Your doctor can recommend the right dosage of this product to best meet your needs. In general, start by taking one dose a day. Gradually increase to three doses per day, if needed or recommeded by your doctor. If minor gas or bloating occurs when you increase doses, try slightly reducing the amount your are taking. This product can be taken any time of day. To establish a routine, we suggest taking it at approximately the same time each day. Also useful for the treatment of gastrointestinal disorders associated with consitipation when recommended by a doctor.

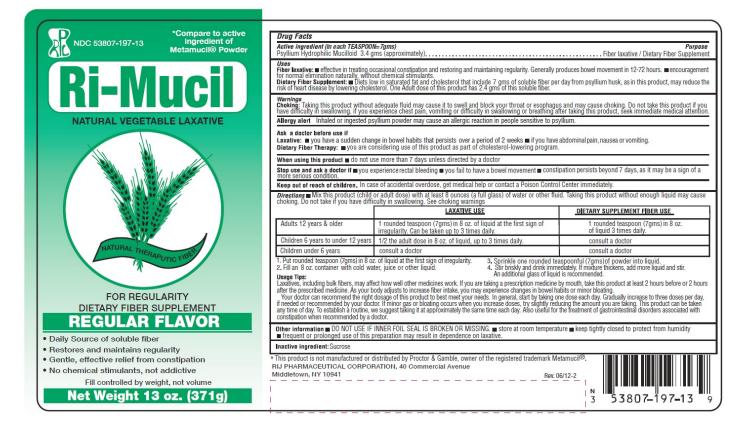
### Other information

- DO NOT USE IF INNER FOIL SEAL IS BROKEN OR MISSING.
- store at room temperature
- keep tightly closed to protect from humidity
- frequent or prolonged use of this prepartion may result in dependence on laxative.

#### **Inactive Ingredients**

Sucrose

### **Product Label**



# **RI MUCIL**

psyllium dietary fiber supplement granule, for solution

Product Information								
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:53807-197				
Route of Administration	ORAL							
Active Ingredient/Active Moiety								
Ing	Basis of Strength		Strength					
PSYLLIUM HUSK (UNII: 0SH053407G) (PSYLLIUM HUSK - UNII:0SH053407G)			PSYLLIUM HUSK 3.4 g in		3.4 g in 100 g			
Inactive Ingredients								
I	ngredient Name			Stren	gth			

SUCROSE (UNII: C151H	8 M554)				
Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
<b>I</b> NDC:53807-197-13	371 g in 1 BOX; Type 0: Not a Combination Product	03/16/1999			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not fina	ıl part334	03/16/1999			

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Rij Pharmaceutical Corporation		144679156	manufacture(53807-197)				

Revised: 4/2018

Rij Pharmaceutical Corporation