

FIBER THERAPY REGULAR FLAVOR - psyllium dietary fiber supplement granule, for solution

Kinray LLC

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.

Drug Facts

Active Ingredients (in each teaspoon = 5.4 g)

Psyllium Powder 3.4 gms (approximately)

Purpose

Fiber Laxative / Fiber Supplement

Uses

Fiber Laxative

- effective in treating occasional constipation and restoring regularity

Fiber Supplement

- daily fiber supplement
- for lowering cholesterol to promote heart health. Diets low in saturated fat and cholesterol that includes 7 grams of soluble fiber per day from psyllium powder, 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. Consult a doctor if you are considering use of this product as part of a cholesterol-lowering program.

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

- The product may cause allergic reaction in people sensitive to inhaled or ingested psyllium.

Ask a doctor before use if you have

- a sudden change in bowel habits that persists over a period of 2 weeks
- abdominal pain, nausea, or vomiting

Stop use and ask a doctor if

- constipation lasts more than 7 days
- rectal bleeding occurs
- These may be signs of a serious condition.

Keep out of reach of children

In case of overdose, contact a doctor or a Poison Control Center right away

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. Stir briskly and drink promptly. If mixture thickens, add more liquid and stir.

	LAXATIVE USE	DIETARY SUPPLEMENT FIBER USE
Adults 12 years & older	1 rounded teaspoon (5.4 g) in 8 oz. of liquid at the first sign of irregularity. Can be taken up to 3 times daily	1 rounded teaspoon (5.4 g) in 8 oz. of liquid 3 times daily.
Children 6 years to under 12 years	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 one dose into an empty glass
2. Mix this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid.
3. Taking this product without enough liquid may cause choking. See choking warning.
4. Stir briskly and drink immediately. If mixture thickens, add more liquid and stir. An additional glass of liquid is recommended.

Bulk forming fibers like psyllium 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 body adjusts to increase fiber intake, you may experience changes in bowel habits or minor bloating.

New Users: 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 recommended by your doctor.


Other information

- **DO NOT USE THIS PRODUCT IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.**
- store at room temperature
- keep tightly closed to protect from humidity
- **each teaspoon contains: potassium 30 mg; sodium 5 mg**


Inactive Ingredients

citric acid, and maltodextrin

Product Label



NDC 61715-129-13
Compare to the active ingredients of Metamucil® Sugar Free †




Fiber Therapy

FOR REGULARITY

REGULAR FLAVOR

SUGAR FREE



Net Wt. 10 oz. (283 g)
52 doses
Fill controlled by weight not volume.

†This product is not manufactured or distributed by Proctor & Gamble, owner of the registered trademark Metamucil®. All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.

Drug Facts

Active Ingredients (in each teaspoon = 5.4 g) Purpose
psyllium powder 3.4 g (approximately).....Fiber Laxative

Uses
 effective in treating occasional constipation and restoring regularity

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 swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.
Allergy alert: This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium.
Ask a doctor before use if you have a sudden change in bowel habits that persists over a period of 2 weeks ■ abdominal pain, nausea, or vomiting
Stop use and ask a doctor if ■ constipation lasts more than 7 days ■ rectal bleeding occurs These may be signs of a serious condition
Keep out of reach of children. In case of overdose, contact a doctor or a Poison Control Center right away.

Directions ■ mix this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. Do not take if you have difficulty in swallowing. See choking warnings. Stir briskly and drink promptly. If mixture thickens, add more liquid and stir.

Adults 12 years & older	1 rounded teaspoon (5.4 g) in 8 oz. of liquid at the first sign of irregularity. Can be taken up to 3 times daily. Generally produces effect in 12-72 hours
Children 6 years to under 12 years	1/2 the adult dose in 8 oz. of liquid, up to 3 times daily
under 6 years	Consult a doctor

1. Put one dose into an empty glass.
 2. Mix this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid.
 3. Taking this product without enough liquid may cause choking. See choking warning.
 4. Stir briskly and drink immediately. If mixture thickens, add more liquid and stir.
 Bulk forming fibers like psyllium 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 body adjusts to increased fiber intake, you may experience changes in bowel habits or minor bloating. **New Users:** Your doctor can recommend the right dosage of this product to best meet your needs. In general, start by taking one dose each day. Gradually increase to three doses per day if needed or recommended by your doctor.

Other Information ■ DO NOT USE THIS PRODUCT IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING. ■ store at room temperature ■ keep tightly close to protect from humidity ■ each teaspoon contains: potassium 30 mg; sodium 5 mg

Inactive Ingredients: citric acid and maltodextrin

Fiber supplement information

Uses ■ daily fiber supplement ■ for lowering cholesterol to promote heart health. Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium powder, as in this product, may reduce the risk of heart disease by lowering cholesterol. One adult dose has 2.4 grams of this soluble fiber. Consult a doctor if you are considering use of this product as part of a cholesterol-lowering program.

Warning read entire label, including warning in **Drug Facts**

Directions

Adults 12 years & older	1 rounded teaspoon (5.4 g) in 8 oz. of liquid 3 times daily
under 12 years of age	Consult a doctor

See mixing direction in **Drug Facts**.
Notice: mix this product with at least 8 oz. (a full glass) of liquid. Taking without enough liquid may cause choking. Do not take if you have difficulty swallowing. See Choking Warning. This product is not intended to diagnose, treat, cure or prevent any disease.

Supplement Facts

Serving size: 1 rounded teaspoon (5.4 g)
 Servings per container 52

Amount per serving	%DV*
Calories 20	
Total Carbohydrate 5 g.....	1 %
Dietary Fiber 3 g.....	10 %
Soluble Fiber 2 g.....	†
Sugar 0.0 g.....	†
Sodium 5 mg.....	< 1 %
Potassium 30 mg.....	< 1 %


* Percentage daily values (% DV) are based on a 2,000 calorie diet
 † Daily value not established

Ingredients citric acid, psyllium powder and maltodextrin.

Questions or comments? 1-845-692-5799

Manufactured By: **RLJ PHARMACEUTICAL CORP., 40 COMMERCIAL AVENUE, MIDDLETOWN, NY 10941** Distributed By: **KINRAY, INC., WHITESTONE, NY 11357**
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Rev 07/13



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FIBER THERAPY REGULAR FLAVOR

psyllium dietary fiber supplement granule, for solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1715-129
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PSYLLIUM HUSK (UNII: 0 SHO53407G) (PS YLLIUM HUSK - UNII:0 SHO53407G)	PSYLLIUM HUSK	3.4 g in 5.4 g	
Inactive Ingredients			
Ingredient Name	Strength		
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
Packaging			
#	Item Code	Package Description	Marketing Start Date
1	NDC:6 1715-129-13	283 g in 1 BOX	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/28/2014	

Labeler - Kinray LLC (012574513)

Revised: 9/2014

Kinray LLC