

FIBER THERAPY ORANGE FLAVOR - 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.

Drug Facts

Active Ingredients (in each dose)

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 12 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

Do not use

- laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor
- this product if you have difficulty in swallowing or have any throat problem.

Ask a doctor before use if

Laxative

- you have a sudden change in bowel habits that persists over a period of 2 weeks

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 experience rectal bleeding
- you fail to have bowel movement
- constipation persists beyond 7 days, as it may be a sign of a more serious condition.

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
Adults 12 years & older	1 rounded teaspoon (7gms) in 8 oz. of liquid at the first sign of irregularity. Can be taken up to 3 times daily	1 rounded teaspoon (12 gms) 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 rounded teaspoon 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 teaspoonful 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 body 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 recommended by your doctor. If minor gas or bloating occurs when you increase doses, try slightly reducing the amount you 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 constipation 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 preparation may result in dependence on laxative.



Inactive Ingredients

citric acid, FD&C Yellow#6, flavor and Sucrose

Product Label

NDC 53807-200-13


Compare to Metamucil®
Original Texture Orange†

Fiber Therapy

FOR REGULARITY

ORANGE FLAVOR



Net Wt. 13 oz. (368 g)
Fill controlled by weight not volume.

Drug Facts

Active ingredient (in each dose)
Psyllium Hydrophilic Mucilloid 3.4 gms (approximately) Fiber laxative / Dietary Fiber Supplement

Purpose
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 include 12 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.

Uses

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 an allergic reaction in people sensitive to psyllium.
Do not use: ■ laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor ■ this product if you have difficulty in swallowing or have any throat problem.

Ask a doctor before use if
Laxative: ■ you have a sudden change in bowel habits that persists over a period of 2 weeks
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 experience rectal bleeding ■ you fail to have a bowel movement ■ constipation persists beyond 7 days, as it may be a sign of a more serious condition.

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 without enough liquid may cause choking. Do not take if you have difficulty in swallowing. See choking warnings.

	LAXATIVE USE	DIETARY SUPPLEMENT FIBER USE
Adults 12 years & older	1 rounded tablespoon (12g) in 8 oz. of liquid at the first sign of irregularity. Can be taken up to 3 times daily.	1 rounded tablespoon (12g) 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 rounded tablespoon in 8 oz. of liquid at the first sign of irregularity.
2. Fill an 8 oz. container with cold water, juice or other liquid.
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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. If minor gas or bloating occurs when you increase doses, try slightly reducing the amount you 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 constipation 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 preparation may result in dependence on laxative.

Inactive ingredient: citric acid, FD&C Yellow#6, flavor and Sucrose.

†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.
Manufactured By: RU PHARMACEUTICAL CORP, 40 Commercial Avenue, Middletown, NY 10941
Distributed by: KINRAY, INC, WHITESTONE, NY 11357 L.Rev 01/13



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FIBER THERAPY ORANGE FLAVOR

psyllium dietary fiber supplement granule, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-200
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSYLLIUM HUSK (UNII: 0SHO53407G) (PSYLLIUM HUSK - UNII:0SHO53407G)	PSYLLIUM HUSK	3.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-200-13	368 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 final	part334	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-200)

Revised: 4/2018

Rij Pharmaceutical Corporation