

FIBER LAXATIVE- psyllium husk capsule
Raritan Pharmaceuticals Inc

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.

DRx Choice Fiber Capsules Natural Psyllium Husk

Drug Facts

Active ingredient (in each capsule)

Psyllium husk approximately 0.52 g

Purpose

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 in 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 persisting for 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, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions

- Take this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning.
- **Adults 12 years and older:** 5 capsules with at least 8 ounces of liquid (swallow 1 capsule at a time) at the first sign of irregularity. Can be taken up to 3 times daily. Generally produces effect in 12-72 hours
- **children 12 years and under:** Ask a doctor
- Laxatives, including bulk fibers, may affect how well other medicines work. If you are taking a prescription medication 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.

Other information

- each capsule contains: **potassium 5 mg**
- store at room temperature. Keep tightly closed to protect from humidity
- contains a 100% natural, therapeutic fiber

WARNING: Consuming this product can expose you to chemicals including lead, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

Inactive ingredients

caramel color, edible ink, gelatin, polysorbate 80

PRINCIPAL DISPLAY PANEL - 25 Capsules Label

NDC **68163-119-25**

Compare to the active ingredient in Metamucil® Capsules 3 in 1 MultiHealth Fiber!™*

100% Natural Psyllium Husk

Fiber Capsules

Fiber Laxative/Dietary Supplement

- Helps maintain healthy blood sugar levels as part of your diet**
- Helps lower cholesterol to promote heart health†
- Promotes digestive health**
- Gluten free (may contain trace amounts less than 20 ppm). If you have specific dietary needs, you should consult your doctor before consuming this product.

†See back for information about soluble fiber and heart disease

25 Capsules

Mfg. by: Raritan Pharmaceuticals

8 Joanna Court

East Brunswick, NJ 08816

*This product is not manufactured or distributed by Procter & Gamble, the distributor of Metamucil® Capsules 3 in1 MultiHealth Fiber!™.

DR CHOICE

Compare to the active ingredient in Metamucil® Capsules 3 in 1 MultiHealth Fiber!™*

100% Natural Psyllium Husk

Fiber Capsules

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*See back for information about soluble fiber and heart disease

25 Capsules

Drug Facts When used as a therapy for regularity:

Active ingredient (in each capsule) Purpose
Psyllium husk approximately 0.32 g.....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 in 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 persisting for 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, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions ■ Take this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough liquid may cause choking. See choking warning ■ **Adults 12 years and older:** 5 capsules with 8 ounces of liquid (swallow 1 capsule at a time) at the first sign of irregularity. Can be taken up to 3 times daily. Generally produces effect in 12-72 hours. ■ **Children 12 years and under:** Ask a doctor ■ 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 increased fiber intake, you may experience changes in bowel habits or minor bloating.

Other information ■ each capsule contains: potassium 5 mg ■ store at room temperature. Keep tightly closed to protect from humidity ■ contains a 100% natural, therapeutic fiber

Inactive ingredients caramel color, edible ink, gelatin, polysorbate 80

Mfg. by Raritan Pharmaceuticals, 8 Joanna Court, East Brunswick, NJ 08816

WARNING
Consuming this product can expose you to chemicals including lead, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

LOT: 11925DCLR

EXP:

UNVARNISHED AREA

PEEL HERE



68163119251

Supplement Facts

Serving Size 5 Capsules
Servings Per Container 5

Amount Per Serving	% DV*
Calories 10	
Total Carb. 2 g	1%*
Dietary Fiber 2 g	8%*
Soluble Fiber 2 g	†
Protein < 1 g	
Iron 0.4 mg	2%
Potassium 25 mg	1%

*Percent Daily Values (%DV) are based on a 2,000 calorie diet.
† Daily Value (DV) not established.

Ingredients: Psyllium husk, gelatin, polysorbate 80, caramel color, edible ink.

TAMPER EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS BROKEN OR MISSING

Questions? 1-866-467-2748

When used as a daily fiber supplement:

Directions: Swallow 1 capsule at a time and take in an upright position. Bulk-forming fibers like psyllium husk may affect how well medicines work. Take this product at least 2 hours before or after medicines.

New Users: Start with 1 serving per day; gradually increase to desired daily intake. You may initially experience changes in bowel habits or minor bloating, as your body adjusts to increased fiber intake.

Uses	Directions (Adults 12 yrs and older)
<p>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 husk, as in this product, may reduce the risk of heart disease by lowering cholesterol. One serving of this product has 1.8 grams of this soluble fiber.</p>	5 capsules 4 times daily. Consult your doctor if you are considering use of this product as part of a cholesterol-lowering program.
<p>For maintaining healthy blood sugar levels as part of your diet**</p>	5 capsules 4 times daily. Consult your doctor before use if you are currently using medication to control your blood sugar levels.
<p>For promoting and maintaining digestive health.** For occasional constipation and to help promote and maintain regularity.</p>	2 to 5 capsules up to 4 times daily for fiber supplementation.
For children under 12 yrs.	Consult a doctor.

NOTICE: Take this product with at least 8 ounces (a full glass) of liquid. Taking without enough liquid may cause choking. Do not take if you have difficulty swallowing.
KEEP OUT OF REACH OF CHILDREN
This product has a low glycemic index, a measure of the effect of dietary carbohydrates on blood sugar levels.

Allergy alert: This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium. Contact your doctor BEFORE USING this dietary supplement if you have recently experienced a sudden change in bowel habits persisting for 2 weeks, abdominal pain, nausea or vomiting. STOP USING this dietary supplement and ask a doctor if constipation lasts more than 7 days or rectal bleeding occurs. These may be signs of a serious condition.

GLUTEN FREE (may contain trace amounts less than 20 ppm). If you have specific dietary needs, you should consult your doctor before consuming this product.

*This product is not manufactured or distributed by Procter & Gamble, the distributor of Metamucil® Capsules 3 in 1 MultiHealth Fiber!™.

Capsules are sealed using a band around the middle.

****These statements have not been evaluated by the food and drug administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

STOP PEELING HERE

FIBER LAXATIVE			
psyllium husk capsule			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-119
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Psyllium Husk (UNII: 0SHO53407G) (Psyllium Husk - UNII:0SHO53407G)		Psyllium Husk	0.52 g	
Inactive Ingredients				
Ingredient Name		Strength		
CAMEL (UNII: T9D99G2B1R)				
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
Product Characteristics				
Color	BROWN	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	RP119	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-119-25	25 in 1 BOTTLE; Type 0: Not a Combination Product	04/16/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	04/16/2019		

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023

Raritan Pharmaceuticals Inc