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.

tSee back for information about soluble fiber and heart disease

25 Capsules

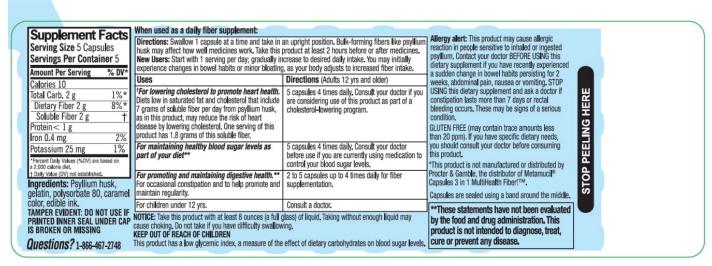
Mfg. by: Raritan Pharmaceuticals

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!™.





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		
CARAMEL (UNII: T9D99G2B1R)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			

Product Characteristics				
Color	BROWN	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	RP119	
Contains				

ı	Pa	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		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