DAILY FIBER SUGAR FREE- psyllium husk powder 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.

100% NATURAL PSYLLIUM HUSK Orange Flavor Sugar free 48 Teaspoon Doses

Drug Facts

Active ingredient: (in each teaspoon)

Psyllium husk approximately 3.4 g

Purpose

Bulk-forming Laxative

Uses:

- for relief of occasional constipation (irregularity)
- generally produces bowel movement in 12-72 hours

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:

Put one dose into an empty glass. 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. See choking warning. Stir briskly and drink promptly. If mixture thickens, add more liquid and stir.

Adults & children	1 rounded teaspoon in 8 ounces of liquid at the first sign of
12 years & older:	irregularity. Can be taken up to 3 times daily.
Children 6-11 yrs :	$\frac{1}{2}$ adult dose in 8 ounces of liquid, up to 3 times daily
Children under 6	Consult a doctor
yrs:	

Bulk-forming fibers like psyllium husk 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.

New Users:

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

Other information:

- each teaspoon contains: potassium 35 mg; sodium 5 mg
- PHENYLKETONURICS: CONTAINS PHENYLALANINE, 25 mg per teaspoon
- store at room temperature. Keep the container tightly closed to protect from humidity
- contains a 100% natural, therapeutic fiber

Inactive ingredients:

aspartame, citric acid, FD&C Yellow 6, maltodextrin, natural and artificial orange flavor, silica.

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

NDC 68163-515-48

Compare to the Fiber Content in Metamucil[®] 4 in 1 MultiHealth Fiber!™* Daily Fiber

100% Natural Psyllium Husk

MultiHealth Daily Fiber Supplement Therapy for Regularity

- Helps you feel less hungry between meals**
- Helps maintain healthy blood sugar levels as part of your diet**
- Helps lower cholesterol to promote heart health†
- Promotes digestive health**
- Gluten free

SUGAR FREE

not a low calorie food

ORANGE SMOOTH

Naturally and Artificially Flavored

48 Teaspoon[‡] Doses

NET WT 10 OZ (283 g)

fill controlled by weight, not volume

Κ

PAREVE

[‡]Serving size varies See DIRECTIONS on back panel for more information

tSee back for information about soluble fiber and heart disease.

**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.

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

*This product is not manufactured or distributed by Procter & Gamble, the distributor of Metamucil[®] 4 in 1 MultiHealth Fiber! $^{\text{\tiny M}}$.

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 has a low glycemic index, a measure of the effect of dietary carbohydrates on blood sugar levels.

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

Manufactured by:

Raritan Pharmaceuticals 8 Joanna Court, East Brunswick, NJ 08816



DAILY FIBER SUGAR FREE

psyllium husk powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-515
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

PSYLLIUM HUSK (UNII: 0SH053407G) (PSYLLIUM HUSK - UNII:0SH053407G) PSYLLIUM HUSK 3.4 g in 5.79 g

Inactive Ingredients		
Ingredient Name	Strength	
ASPARTAME (UNII: Z0H242BBR1)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		

FD&C Yellow No. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	

Product Characteristics			
Color	BROWN (Light Yellowish)	Score	
Shape		Size	
Flavor	ORANGE (natural and artifcial)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		283 g in 1 CANISTER; Type 0: Not a Combination Product	03/12/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/12/2019	

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023 Raritan Pharmaceuticals Inc