FIBER THERAPY ORANGE SMOOTH- psyllium husk powder YOUR MILITARY EXCHANGE

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.

exchange select[™] 100% Natural Psyllium Husk Orange Flavor Sugar free

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

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. As your body adjusts to increased fiber intake, you may experience changes in bowel habits or minor bloating.

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

 $exchange select^{TM}$

NDC# 55301-515-14

Compare to the fiber content in Metamucil[®] 4 in 1 MultiHealth Fiber!^{™*}

Fiber Therapy

100% NATURAL PSYLLIUM HUSK

Multi-benefit 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

114 teaspoon doses[‡]

NET WT 23.3 OZ (1.4 LBS) 660 g

fill controlled by weight, not volume

+See back for information about soluble fiber and heart disease.

\$Serving size varies. See DIRECTIONS on back panel for more information

**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.

*This product is not manufactured or distributed by Procter & Gamble, the distributor of Metamucil [®]. 4 in 1 MultiHealth Fiber! [™].

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

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.

"SASTISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured for Your Military Exchanges

By: Raritan Pharmaceuticals Inc.,

8 Joanna Court,

East Brunswick, NJ 08816

Package Label 114 Teaspoons Doses

Compare to the Fiber Content in Metamucil*	Supplement Facts	When used as a therapy for regularity:
4 in 1 MultiHealth Fiber™*	Supprement Facts Serving Size 2 rounded tsp (11.6g) 1 rounded tsp (5.8g)	Drug Facts
The first for th	Servings Per Container About 57 About 114	Active ingredient (in each teaspoon) Purpose
NDC55301-515-14	Amount per Serving %DV* %DV*	Psyllium husk approximately 3.4 gBulk-forming Laxative
	Calories 45 20 Total Carbohydrate 11 g 4%* 5 g 2%*	Uses for relief of occasional constipation (irregularity) generally produces bowel movement in 12-72 hours
	Dietary Fiber 6 g 24%* 3 g 12%*	
exchange select	Soluble Fiber 5 g † 2 g †	Warnings Choking: Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and
	Total Sugars 0 g + 0 g +	may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain,
	Includes Added Sugars 0 g † 0 g † Iron 1.4 mg 8% 0.7 mg 4%	vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.
	Sodium 1.4 mg 0.6 0.7 mg 4.6 10 mg <1% 5 mg <1%	Allergy alert: This product may cause an allergic reaction in people sensitive to inhaled or ingested psyllium.
	Potassium 70 mg 1% 35 mg 1%	Ask a doctor before use if you have ■ a sudden change in bowel habits persisting for 2 weeks ■ abdominal pain, nausea or vomiting
	*Percent Daily Values (%DV) are based on a 2,000 calorie diet. † Daily Value (DV) not established.	Stop use and ask a doctor if I constipation lasts more than 7 days II rectal bleeding occurs
Fiber Therapy	Ingredients: Psyllium Husk, Maltodextrin, Citric Acid, Natural &	These may be signs of a serious condition.
	Artificial Orange Flavor, Silica, Aspartame, FD&C Yellow No. 6.	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.
100% Natural Psyllium Husk	Notice: Put 1 dose of product into an empty glass. Mix this product with	
	at least 8 ounces (a full glass) of liquid. Stir briskly and drink promptly. Taking without enough liquid may cause choking. Do not take if you	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
Multi-benefit Daily Fiber Supplement	have difficulty swallowing.	varning. Stir briskly and drink promptly. If mixture thickens, add more liquid may cause choking. See choking
Therapy For Regularity	Allergy alert: This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium. Contact your doctor BEFORE	Adults & children 12 years 1 rounded teaspoon in 8 ounces of liquid at the first sign of irregularity.
nicrupy for negativity	USING this dietary supplement if you have recently experienced a	& older: Can be taken up to 3 times daily.
• Helps you feel less hungry between meals"	sudden change in bowel habits persisting for 2 weeks, abdominal pain, nausea or vomiting. STOP USING this dietary supplement and ask a	Children 6-11 yrs: 1/2 adult dose in 8 ounces of liquid, up to 3 times daily
Helps maintain healthy blood sugar levels	doctor if constipation lasts more than 7 days or rectal bleeding occurs.	Children under 6 yrs: Consult a doctor
as part of your diet*	These may be signs of a serious condition. New Users: Start with 1 serving per day; gradually increase to desired	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.
	daily intake. You may initially experience changes in bowel habits or	New Users: Start with 1 serving per day; gradually increase to desired daily intake. You may initially experience
 Helps lower cholesterol to promote heart health[†] 	minor bloating, as your body adjusts to increased fiber intake.	changes in bowel habits or minor bloating, as your body adjusts to increased fiber intake.
Promotes digestive health"	When used as a daily fiber supplement:	Other information
• Gluten free	Fiber Supplement Information	each teaspoon contains: potassium 35 mg; sodium 5 mg PHENYLKETONURICS: CONTAINS PHENYLALANINE, 25 mg per teaspoon
	Uses & Directions:	store at room temperature. Keep the container tightly closed to protect from humidity
Sugar Free not a low calorie food	For feeling less hungry between meals** Adults & children 12 yrs. and over: Two rounded teaspoons in	■ contains a 100% natural, therapeutic fiber
	8 or more ounces of liquid with meals, up to 3 times daily.	Inactive ingredients aspartame, citric acid, FD&C Yellow No. 6, maltodextrin, natural and artificial orange flavor, silica.
Orange Smooth	For lowering cholesterol to promote heart health [†] Adults & children 12 yrs. & over: One rounded teaspoon in	Ouestions or comments? 1-866-467-2748
	8 ounces of liquid, 3 times daily. *Diets low in saturated fat and	*This product is not manufactured or distributed by Procter & Gamble, the distributor of Metamucil [®] 4 in 1 MultiHealth Fiber!™.
Naturally and Artificially Flavored	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	
toognoon A	lowering cholesterol. One serving of this product has 2.4 grams of this	FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT
1 1 <u>d</u> teaspoon	soluble fiber. Consult a doctor if you are considering use of this product as a part of a cholesterol-lowering program.	DISEASE. Manufactured For Your Military Exchanges
$114_{\text{doses}^{\dagger}}^{\text{teaspoon}}$	For maintaining healthy blood sugar levels as part of	AwaRNING Consuming this product can expose you to chemicals including lead, which is known 8 Joanna Court.
	your diet**	to the State of California to cause cancer. For more information, go to www. <u>PSSWamings.ca.gov.</u> East Brunswick, NJ 08816
NET WT 23.3 OZ (1.4 LBS) 660 g	Adults & children 12 yrs. and over: One rounded teaspoon in 8 ounces of liquid, 3 times daily. Consult your doctor before use if you are currently using medication to control your blood sugar levels.	TAMPER EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS BROKEN OR MISSING
	For promoting and maintaining digestive health**	GLUTEN FREE (may contain tace amounts less than 20 nom) if you have specific ristory
See back for information about soluble poler and near alsolate Serving size varies. See DIRECTIONS on back panel for more information.	Adults & children 12 yrs. and over: One rounded teaspoon in 8 ounces of liquid up to 3 times daily for fiber supplementation.	GUITS FREE (may contain tace amounts less than 20 pm) four have seek (delay needs, you should contail your adout batter consuming this produkt.
**THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD	For occasional constipation and to help promote and maintain regularity.	This product has a low glycemic index. a measure of the effect of devary carbohydrates
AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.	For children under 12 yrs: consult a doctor.	on blood sugar levels.
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	60 0 TH	
FIBER THERAPY ORANGE SM	HTOON	
psyllium husk powder		

Product Infor	mation					
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:55301-515	
Route of Admini	stration	ORAL				
Active Ingred	ient/Active Moi	ety				
Ingredient Name Basis of Str					rength	Strength
PSYLLIUM HUSK (UNII: 0 SHO53407G) (PSYLLIUM HUSK - UNII:0 SHO53407G) PSYLL			PS YLLIUM HUS	SK	3.4 g in 5.8 g	
Inactive Ingre	dients					
mactive mgre		× 11				
ASPARTAME (UNII: Z0 H242BBR1)					S	trength
ASPARTAME (UN	II: Z0H242BBR1)	Ingredient Name			S	trength
	II: Z0H242BBR1) ` RIC ACID (UNII: XF4				S	trength
ANHYDRO US CIT	,	417D3PSL)			S	trength
ANHYDROUS CIT FD&C Yellow No.	TRIC ACID (UNII: XF	417D3PSL) 8)			S	trength
ANHYDROUS CIT FD&C Yellow No. MALTO DEXTRIN	FRIC ACID (UNII: XF4 6 (UNII: H77VE193A	417D3PSL) 8)			S	trength
ANHYDROUS CIT FD&C Yellow No. MALTO DEXTRIN	F RIC ACID (UNII: XF4 6 (UNII: H77VEI93A 1 (UNII: 7CVR7L4A2C	417D3PSL) 8)			S	trength
ANHYDROUS CIT FD&C Yellow No. MALTODEXTRIN SILICON DIOXID	`RIC ACID (UNII: XF4 6 (UNII: H77VEI93A 1 (UNII: 7CVR7L4A2E E (UNII: ETJ7Z6 XBU	417D3PSL) 8)			S	trength
ANHYDROUS CIT FD&C Yellow No. MALTO DEXTRIN	`RIC ACID (UNII: XF4 6 (UNII: H77VEI93A 1 (UNII: 7CVR7L4A2E E (UNII: ETJ7Z6 XBU	417D3PSL) 8) 9) 4)	Sco	pre	S	trength

Flavor	(DRANGE	Imprint Code	
Contains				
Packaging				
# Item Code		Package Description	Marketing Start Date	Marketing End Date
1 NDC:55301-515- 14	660 g Produ	in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	05/13/2019	
Marketing Information				
Marketing Cates	gory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not	final	part334	0 5/13/20 19	

Labeler - YOUR MILITARY EXCHANGE (001695568))
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