

**NATURAL FIBER POWDER SMOOTH TEXTURE- psyllium husk granule**  
**Physicians Total Care, 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.*

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Active ingredient (in each dose)

Psyllium Hydrophilic Mucilloid 3.4 grams

Purpose

Bulk-Forming Laxative

Use For relief of occasional constipation. Generally produces effect in 12-72 hours. Natural bulk producing fiber encourages normal elimination without chemical stimulants.

Warnings Allergy alert Inhaled or ingested psyllium powder may cause an allergic reaction in people sensitive to psyllium. 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.

Do not use laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor.

Ask a doctor before use if you have - a sudden change in bowel habits that persists over a period of two weeks.

When using this product - do not take for a period longer than 1 week, unless directed by a doctor

Stop use and ask a doctor if - you experience rectal bleeding - you fail to have a bowel movement

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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. See choking warnings. Adults and children 12 years and over: sprinkle one dose, 1 rounded tablespoonful (12g), in 8 oz of liquid, 1-3 times daily. Children 6 years to under 12 years: 1/2 the adult dose in 8 oz of liquid, up to 3 times daily. Children under 6 years: Consult a doctor.

Other information - each 12 g dose contains: Calcium 6 mg, Potassium 31 mg, Sodium 3 mg - store below 86 Degree F (30 Degree Centigrade) - keep container tightly closed - protect from excessive moisture - tamper-evident bottle mouth sealed for your protection - do not use if imprinted inner seal is broken or missing - laxatives, including bulk fibers, may affect how other medicines work, wait 1-2 hours before or after taking other medicines. - can be taken 1 to 3 times daily, before or after meals, mornings, or evenings - maximum daily dose (3 tablespoonfuls) is very low sodium - do not discard Konsyl Orange powder into any plumbing systems - note to diabetics: this product contains 66% sugar (sucrose) - each dose provides 3 grams total dietary fiber - each dose contains 35 calories

Inactive ingredients citric acid, D and C yellow No. 10 and FD and C Yellow No.6 (Sunset Yellow), flavoring, sucrose.

Questions? Call Konsyl Pharmaceuticals, Inc. at 1-800-36-6795 8:30 a.m to 5 p.m. ET.

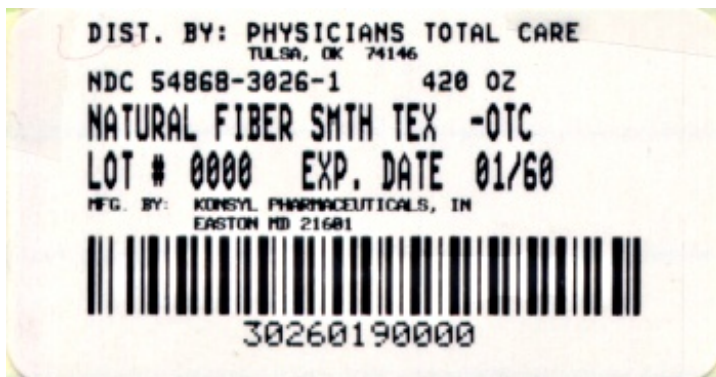
When using this product physicians recommend a gradual increase in dietary fiber. If minor gas or bloating occurs, begin with a increase the dose over several days. Always follow with 8 oz. of fluid. Manufactured by Konsyl Pharmaceuticals, Inc. Easton, MD 21601 [www.konsyl.com](http://www.konsyl.com) Konsyl

Pharmaceuticals, Inc. 33792 0810 Dietary Fiber Supplement Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium husk may reduce the risk of Coronary Heart Disease (CHD) by lowering cholesterol. ONE ADULT DOSE OF THIS PRODUCT CONTAINS 2.0 GRAMS OF THIS SOLUBLE FIBER = 3.4 G OF PSYLLIUM Dosage Adults 12 years and older: 1 Rounded teaspoonful in 8 oz. of fluid 2 TIMES DAILY, follow with additional fluid to aid product action, before or after meals, mornings or evenings. Children under 12 years: Consult a doctor. Notice Ask a doctor before use if you consider taking this product as part of a cholesterol-lowering program. See directions for use before taking this product. Supplements Facts Serving size (dose): 1 rounded teaspoonful psyllium 3.4g Serving per container 45 Amount Per Serving %DV\* Calories (Available) 35 Sodium 0% Carbohydrates (Available) 8g 3% Dietary Fiber 3g 11% Soluble Fiber 2g - Sugars 8g - Calcium 0% Iron 6% \*Percent Daily Values (DV) are based on a 2,000 calorie diet. - Daily Value (DV) not established.

Psyllium Hydrophilic Mucilloid Smooth Texture Gluten Free Helps Lower Cholesterol NET WEIGHT 12.0g K PAREVE SUPPLEMENTS / LAXATIVE TAMPER-EVIDENT PACKAGE. DO NOT USE IF OPENED OR DAMAGED. DIRECTIONS FOR USE: MIX THIS PRODUCT (CHILD OF 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 WARNINGS. 1. Sprinkle one packet into a shaker or glass containing 8 oz. of cool water. 2 Cover. Shake well for 3-5 seconds, or stir well. 3. Drink promptly. If mixture thickens, add more liquid and stir. Follow with additional liquid to aid product action. DOSAGE: Adults and children 12 years of age and over: One packet (or dose) 1 to 3 times daily, before or after meals, or as directed by a doctor. Children 6 to under 12 years of age: 1/2 adult dose, or as directed by a doctor. Children under 6 years of age: Consult a doctor. INDICATIONS: For relief of occasional constipation (irregularity). This product generally produces bowel movement in 12 to 72 hours. See insert or carton for complete WARNINGS. ALLERGY ALERT: Inhaled or ingested psyllium powder may cause an allergic reaction in people sensitive to psyllium.

Manufactured by Konsyl Pharmaceuticals, Inc. Easton, MD 21601 Store below 86 Degree F (30 Degree Centigrade) 3 02241 85200 5

Additional barcode labeling by: Physicians Total Care, Inc., Tulsa, Oklahoma 74146  
NDC 54868-3026-1



Natural Fiber Smooth Texture Powder

Psyllium Hydrophilic Mucilloid Heart Healthy Smooth Texture

Gluten Free Helps Lower Cholesterol

K PAREVE Naturally Sweetened SUPPLEMENTS / LAXATIVE

NET WEIGHT 538 (19oz)

(FILL CONTROLLED BY WEIGHT NOT VOLUME)

## NATURAL FIBER POWDER SMOOTH TEXTURE

psyllium husk granule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54868-3026(NDC:0224-1852)
<b>Route of Administration</b>	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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SUCROSE (UNII: C151H8M554)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3026-1	538 g in 1 CANISTER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part334	03/31/2011	

**Labeler** - Physicians Total Care, Inc. (194123980)

### Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 1/2012

Physicians Total Care, Inc.