FIBER THERAPY ORANGE FLAVOR - psyllium dietary fiber supplement granule, for solution Kinray LLC

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.

Drug Facts

Active Ingredients (in each teaspoon = 5.4 g)

Psyllium Powder 3.4 gms (approximately)

Purpose

Fiber Laxative / Fiber Supplement

Uses

Fiber Laxative

• effective in treating occasional constipation and restoring regularity

Fiber Supplement

- daily fiber supplement
- for lowering cholesterol to promote heart health. Diets low in saturated fat and cholesterol that includes 7 grams of soluble fiber per day from psyllium powder, as in this product, may reduce the risk of heart disease by lowering cholesterol. One Adult dose of this product has 2.4 gms of this soluble fiber. Consult a doctor if you are considering use of this product as part of a chloesterol-lowering program.

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

• The 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 that persists over a period of 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, contact a doctor or 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 with enough liquid may cause choking. Do not take if you have difficulty in swallowing. See choking warnings. Stir briskly and drink promptly. if mixture thickens, add more liquid and stir.

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	LAXATIVE USE	DIETARY SUPPLEMENT FIBER USE
5	1 rounded teaspoon (5.4 g) in 8 oz. of liquid at the first sign of irregularity. Can be taken up to 3 times daily	1 rounded teaspoon (5.4 g) in 8 oz. of liquid 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	consult a doctor
Children under 6 years	consult a doctor	consult a doctor

- 1. Put one dose into an empty glass
- 2. Mix this product (child or adult dose) with at least 8 ounces (a full glass) of water or other fluid.
- 3. Taking this product without enough liquid may cause choking. See choking warining.
- 4. Stir briskly and drink immediately. If mixture thickens, add more liquid and stir. An additional glass of liquid is recommended.

Bulk forming fibers like psyllium 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 increase fiber intake, you may experience changes in bowel habits or minor bloating.

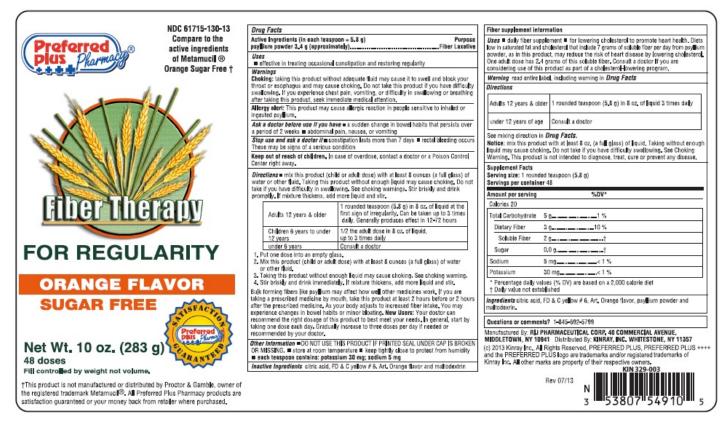
New Users: Your doctor can recommend the right dosage of this product to best meet your needs. In general, start by taking one dose a day. Gradually increase to three doses per day, if needed or recommeded by your doctor.

Other information

- DO NOT USE THIS PRODUCT IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.
- store at room temperature
- keep tightly closed to protect from humidity
- each teaspoon contains: potassium 30 mg; sodium 5 mg

Inactive Ingredients

Product Label



FIBER THERAPY ORANGE FLAVOR

psyllium dietary fiber supplement granule, for solution

Product Inform	nation						
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:61	NDC:61715-130	
Route of Adminis	tration	ORAL					
Active Ingredie	ent/Active Moi	ety					
	Ing	redient Name		Basis of Str	ength	Strength	
PSYLLIUM HUSK (UNII: 0SHO53407G) (PSYLLIUM HUSK - UNII:0SHC	53407G)	PS YLLIUM HUS	šК	3.4 g in 5.4 g	
PSYLLIUM HUSK (Inactive Ingred) (PSYLLIUM HUSK - UNII:0SHC	53407G)	PS YLLIUM HUS	SK	3.4 g in 5.4 g	
) (PSYLLIUM HUSK - UNII:0 SHC Ingredient Name	53407G)	PS YLLIUM HUS		3.4 g in 5.4 g Strength	
	lients	Ingredient Name	53407G)	PS YLLIUM HUS			
Inactive Ingred	lients UNII: 7CVR7L4A2D	Ingredient Name	53407G)	PS YLLIUM HUS			
Inactive Ingred MALTODEXTRIN (lients UNII: 7CVR7L4A2D OHYDRATE (UNII:	Ingredient Name) 2968PHW8QP)	53407G)	PS YLLIUM HUS			
Inactive Ingred Maltodextrin (Citric Acid Mon	lients UNII: 7CVR7L4A2D OHYDRATE (UNII:	Ingredient Name) 2968PHW8QP)	53407G)	PS YLLIUM HUS			
Inactive Ingred Maltodextrin (Citric Acid Mon	lients UNII: 7CVR7L4A2D OHYDRATE (UNII: D.6 (UNII: H77VEI9	Ingredient Name) 2968PHW8QP)	53407G)	PS YLLIUM HUS			

Shape			Size				
Flavor	ORANGE		Imprint Code				
Contains							
Packaging							
# Item Code	Package Description	Marketing	Start Date	Ma	arketing End Date		
1 NDC:61715-130-13	283 g in 1 BOX						
Marketing Information							
Marketing Category	Application Number or Monog	raph Citation	Marketing Star	t Date	Marketing End Date		
OTC monograph not final	part334		09/28/2014				

Labeler - Kinray LLC (012574513)

Revised: 9/2014

Kinray LLC