SUNMARK FIBER SMOOTH TEXTURE - psyllium husk powder, for suspension McKesson

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.

Sunmark Fiber Smooth texture Sugar free Orange flavor

Active ingredient (per each rounded teaspoon=5.8 g)

psyllium husk 3.4 g

Purpose

Bulk-forming laxative

Uses

effective in treating occasional constipation and restoring regularity

Warnings

Allergy alert: May cause allergic reaction in people sensitive to ingested or inhaled 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.

Ask a doctor before use if you have

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits persisting for 2 weeks

Ask a doctor or pharmacist before use if you are

taking any other drug. Laxatives may affect how other drugs work.

When using this product

- do not exceed the maximum recommended daily dosage in a 24-hour period
- you may experience changes in bowel habits or minor bloating as your body adjusts to increased fiber intake

Stop use and ask a doctor if

- constipation lasts more than 7 days
- rectal bleeding occurs

These could 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.

Directions

- take at the first sign of irregularity up to 3 times a day
- put one dose into an empty glass
- fill glass with 8oz of water or favorite beverage
- stir briskly and drink promptly
- if mixture thickens add more water and stir
- take 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.
- 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 dose per day; gradually increase to 3 doses per day as necessary

adults and children 12 years and over	1 rounded teaspoon
6 to under 12 years	1/2 teaspoon
under 6 years	ask a doctor

Other information

- each teaspoon contains: potassium 30 mg and sodium 5 mg
- **Phenylketonurics:** contains phenylalanine 25 mg per teaspoon
- store at (20°-25°C) 68°-77°F

Inactive ingredients

aspartame, citric acid, FD and C yellow 6, maltodextrin, natural and artificial orange flavor, silicon dioxide.

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

Fiber Supplement Information

Uses Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium seed husk, may reduce the risk of heart disease by lowering cholesterol levels. One ADULT serving provides 2.4 grams of soluble fiber. Consult a doctor if you are considering use of the products as part of a cholesterol-lowering program.

Warnings Read entire label, including warnings in Drug Facts

Directions Adults 12 years and older: 1 rounded TEASPOON (tsp) in 8 oz of liquid 3 times daily.

Children under 12 years: Consult a doctor.

NOTICE: Mix this product with at least 8 ounces (a full glass) of liquid. Taking this product without enough liquid may cause choking. Do not take if you havbe difficulty swallowing. **See choking warning.**

PDP

Sunmark

Compare to the active ingredient in Metamucil®

fiber Smooth Texture Sugar Free

Bulk-forming laxative and Dietary fiber supplement 100% Natural Psyllium Seed Husk Fiber

Orange Flavor

Naturally and Artificially Flavored

net wt 10 oz (283 g)

48 teaspoon doses





2%*

12%

4%

<1%

<1%

SUNMARK FIBER SMOOTH TEXTURE

psyllium husk powder, for suspension

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-090	
Route of Administration	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 5.8 g

Inactive Ingredients		
Ingredient Name	Strength	
ASPARTAME (UNII: Z0H242BBR1)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics		
Color	bro wn	Score
Shape		Size
Flavor	ORANGE	Imprint Code
Contains		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:49348-090-92	283 g in 1 CANISTER			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/27/2006	

Labeler - McKesson (177667227)

Revised: 9/2012 McKesson