

ORIGINAL TEXTURE ORANGE FLAVOR - psyllium husk powder, for suspension

Sunmark

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 Original Texture Orange Flavor

Active ingredient (per each rounded tablespoon=11 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 tablespoon
6 to under 12 years	1/2 tablespoon
under 6 years	ask a doctor

Other information

- each tablespoon contains: potassium 30 mg and sodium 5 mg
- store at (20°-25°C) 68°-77°F

Inactive ingredients

citric acid, FD and C yellow 6, natural and artificial flavor, silicon dioxide, sucrose

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

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 TABLESPOON (tbsp) 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 have difficulty swallowing. **See choking warning.**

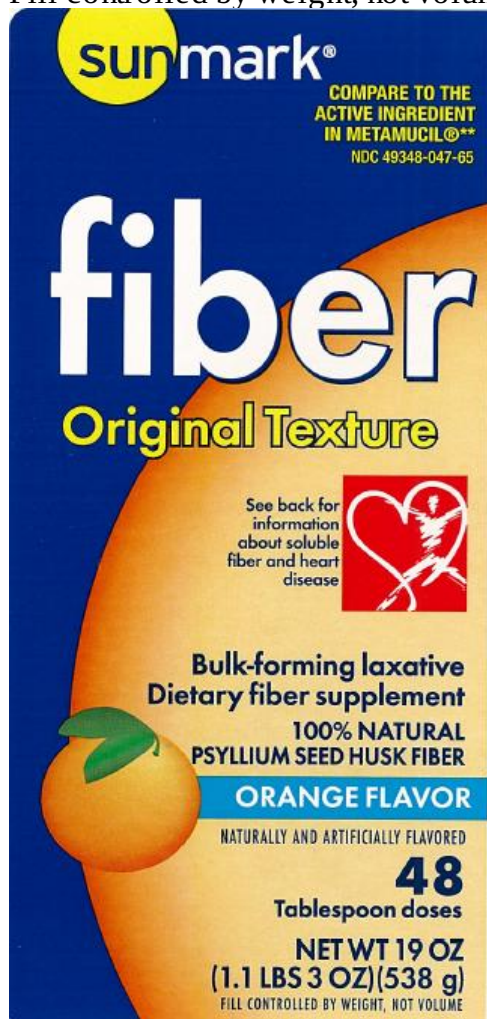
PDP

Sunmark

compare to the active ingredient in Metamucil®

fiber Original Texture

Bulk-forming laxative
 Dietary fiber supplement
 100% Natural Psyllium Seed Husk Fiber
 Orange Flavor
 Naturally and Artificially Flavored
 48 Tablespoon doses
 Net wt 19 oz (1.1 LBS 3 OZ) (538 g)
 Fill controlled by weight, not volume



READ ENTIRE LABEL INCLUDING WARNINGS IN DRUG FACTS.

FIBER LAXATIVE	DIETARY FIBER SUPPLEMENT																		
<p style="text-align: center;">NOTE SEPARATE USES ▶</p> <p>Drug Facts</p> <p>Active ingredient (per each rounded tablespoon = 11 g) Psyllium husk 3.4 g.....Bulk-forming laxative</p> <p>Purpose Bulk-forming laxative</p> <p>Uses ■ effective in treating occasional constipation and restoring regularity</p> <p>Warnings Allergy alert: May cause allergic reaction in people sensitive to ingested or inhaled psyllium</p> <p>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.</p> <p>Ask a doctor before use if you have ■ abdominal pain, nausea or vomiting ■ a sudden change in bowel habits persisting for 2 weeks</p> <p>Ask a doctor or pharmacist before use if you are taking any other drug. Laxatives may affect how other drugs work.</p> <p>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</p> <p>Stop use and ask a doctor if ■ constipation lasts more than 7 days ■ rectal bleeding occurs These could be signs of a serious condition.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶</p>	<p>Drug Facts (continued)</p> <p>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.</p> <p>■ If you are taking a prescription medicine by mouth, take this product at least 2 hours before or 2 hours after the prescribed medicine.</p> <p>■ New Users: Start with 1 dose per day; gradually increase to 3 doses per day as necessary</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">adults and children 12 years and over</td> <td style="width: 50%;">1 rounded tablespoon</td> </tr> <tr> <td>6 to under 12 years</td> <td>1/2 tablespoon</td> </tr> <tr> <td>under 6 years</td> <td>ask a doctor</td> </tr> </table> <p>Other information ■ each tablespoon contains: potassium 30 mg and sodium 5 mg ■ store at (20°-25°C) 68°-77°F</p> <p>Inactive ingredients citric acid, FD&C yellow #6, natural and artificial orange flavor, silicon dioxide, sucrose.</p> <p style="text-align: center;">DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR BROKEN</p> <p style="text-align: center;">**This product is not manufactured or distributed by Procter & Gamble, the distributor of METAMUCIL®.</p> <p style="text-align: center;">McKesson Empowering Healthcare</p> <p>Another Quality Product Distributed By McKesson One Post Street, San Francisco, CA 94104 Money Back Guarantee Please visit us at www.sunmarkbrand.com</p> <p style="text-align: right;">LOT: EXP:</p>	adults and children 12 years and over	1 rounded tablespoon	6 to under 12 years	1/2 tablespoon	under 6 years	ask a doctor												
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psyllium husk powder, for suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49 348-047
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSYLLIUM HUSK (UNII: 0 SHO5340 7G) (PSYLLIUM HUSK - UNII:0 SHO5340 7G)	PSYLLIUM HUSK	3.4 g in 11 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-047-65	538 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 - Sunmark (177667227)

Revised: 9/2012

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