

SMOOTH TEXTURE ORANGE FLAVOR - psyllium husk powder, for suspension
HEALTH MART

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.

Health Mart Fiber Powder

Active ingredient (per each rounded tablespoon=12 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

Health Mart Pharmacy

compare to Metamucil® active ingredient

fiber powder

psyllium husk 3.4 g
 bulk-forming laxative
 dietary fiber supplement
 helps maintain and restore regularity
 orange flavor smooth texture
 net wt 20.3 oz (575 g) 48 tablespoon doses



NDC 62011-0133-1

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FIBER LAXATIVE	DIETARY FIBER SUPPLEMENT																		
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<p>Directions FOR USE:</p> <ol style="list-style-type: none"> Place the seal of a 12 grams filled in directions into an empty glass. Fill glass with at least 8 ounces of non-carbonated beverage. Stir briskly. If the mixture thickens, add more water and stir again. 																			

MFR 62041 REV 1211



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Fill controlled by weight, not volume.

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LOT: _____

EXP: _____

SMOOTH TEXTURE ORANGE FLAVOR			
psyllium husk powder, for suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:620 11-0 133
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 12 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:620 11-0133-1	575 g in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/21/2012	

Labeler - HEALTHMART (177667227)