

MUCILIN SF- psyllium (ispaghula) husk powder
Paradigm Pharmaceuticals 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.

MUCILIN SF

Active Ingredient

Container Pack :

Psyllium (Ispaghula) husk 3.5 g in one Teaspoonful

Sachet Pack :

Psyllium (Ispaghula) husk 3.5 g in one Sachet

Purpose

Fiber therapy for healthy bowel regularity

Uses

- Treatment of occasional constipation to restore healthy bowel regularity

Warnings

Choking: The product should be taken with at least one full glass (8 oz) of liquid. Without enough liquid it may swell and obstruct throat and esophagus and cause choking. If you have difficulty in swallowing do not take this product. In taking the product if you feel difficulty in swallowing, breathing problems, chest pain, vomiting, seek immediate medical attention.

Allergy alert: Allergic reactions may occur in those sensitive to inhaling or ingesting psyllium husk.

Consult a doctor before use:

- if you have a sudden change in bowel functions that persists for ten days or more
- if you suffer from abdominal pain, nausea or vomiting.

Discontinue and ask a doctor if

- your constipation lasts seven days or more
- you experience rectal bleeding

Either of these may be a sign of a serious medical condition.

Keep out of reach of children. The product should be administered to children under adult supervision; and in case of child overdose.

Contact a physician or a poison control center immediately.

Directions

Directions for Container pack

Mix one teaspoonful of Mucilin briskly with at least one full glass (8 oz) of water or other liquid such as fruit juice or milk and drink immediately. Take another glass of fluid. Without sufficient liquid, the natural swelling of the product may cause choking. Please see **Warnings**. Do not take the product just before bedtime, or while lying down.

Adults 12yrs. & older	1 teaspoonful in 8 oz of liquid, may be taken 3 times a day.
Children 6 - 11 yrs.	½ of adult dose may be taken 3 times a day.
Under 6 yrs.	Not recommended, but consult a doctor.
New Users	Start with 1 dose per day, gradually increase to 3 as necessary.

Product normally effects within 12 hrs. - 48 hrs.

Due to increased fiber intake you may experience minor bloating, and change in bowel routine.

Directions for Sachet pack

Mix one sachet of Mucilin briskly with at least one full glass (8 oz) of water or other liquid such as fruit juice or milk and drink immediately. Take another glass of fluid. Without sufficient liquid, the natural swelling of the product may cause choking. Please see **Warnings**. Do not take the product just before bedtime, or while lying down.

Adults 12yrs. & older	1 sachet in 8 oz of liquid, may be taken 3 times a day.
Children 6 - 11 yrs.	½ of adult dose may be taken 3 times a day.
Under 6 yrs.	Not recommended, but consult a doctor.
New Users	Start with 1 dose per day, gradually increase to 3 as necessary.

Product normally effects within 12 hrs. - 48 hrs.

Due to increased fiber intake you may experience minor bloating, and change in bowel routine.

Other Information

Container Pack :

One teaspoonful contains: sodium 6 mg

Phenylketonurics: Contains Phenylalanine (20 mg per teaspoonful)
Store at room temperature. Tightly close the bottle to protect from humidity
Contains 100% natural soluble fiber

Sachet Pack

One sachet contains: sodium 6 mg
Phenylketonurics: Contains Phenylalanine (20 mg per sachet)
Store at room temperature.
Contains 100% natural soluble fiber.

Inactive Ingredients

Acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, FD&C Yellow No. 6, mannitol, orange flavor, sodium chloride

Questions?

Questions? Call toll free: 833-MUCILIN ®

SPL UNCLASSIFIED SECTION

Imported and Distributed by:

Paradigm Pharmaceuticals Inc.

501 Fifth Avenue, Suite 701,
New York, New York 10017, U.S.A.

Under license from:

Paradigm Pharmaceuticals Inc., U.S.A.

Manufactured by:

Berlin Pharmaceutical Industry Co., Ltd.
Bangkok, Thailand

Product Label

Mucilin SF

ORANGE FLAVOR SUGAR FREE

Best Before

Psyllium (Ispaghula) Husk 100%

Natural 100% Soluble Fiber

Mfg. Date

- Healthy Heart**
- Blood Sugar Control*
- Colon Health/Bulk Laxative*
- Appetite Control Between Meals*

DAILY FIBER SUPPLEMENT
Manufactured Under Pharmaceutical Control*

LOT PARADIGM
PHARMA NUTRACEUTICALS

Imported and Distributed by:
Paradigm Pharmaceuticals Inc.
501 Fifth Avenue, Suite 701,
New York, New York 10017, U.S.A.

NET WT 0.18 OZ (5 g)

Manufactured by:
Berlin Pharmaceutical Industry Co., Ltd.
222 Romkiao Road, Klongsampravel,
Latkrabang, Bangkok 10520, Thailand

Mucilin SF

ORANGE FLAVOR SUGAR FREE

Each sachet (5 g) contains:
Psyllium (Ispaghula) husk powder 3.5 g

Dosage:

Adults: One sachet 3 times a day
Children 6 -12 years: half the adult dose
New User: Start with 1 sachet a day, gradually increase to 3 a day

Precaution:

- Take it with sufficient liquid (See Directions)
- Do not mix in hot water
- Drink immediately; avoid if it turns into jelly when left too long before consuming
- Do not consume at bedtime
- Do not consume if you have problem swallowing, or experience abdominal pain, nausea or vomiting

Phenylketonurics : Contains Phenylalanine

Store at room temperature

NET WT 0.18 OZ (5 g)

† US FDA, CITE: 21CFR101.81

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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Supplement Life



Drug Facts

Active ingredient (in one Teaspoonful) Psyllium (ispaghula) husk 3.5 g
Purpose Fiber therapy for healthy bowel regularity

Uses
 • Treatment of occasional constipation to restore healthy bowel regularity

Warnings
Choking: The product should be taken with at least one full glass (8 oz) of liquid. Without enough liquid it may swell and obstruct throat and esophagus and cause choking. If you have difficulty in swallowing do not take this product. In taking the product if you feel difficulty in swallowing or breathing problems, chest pain and vomiting, seek immediate medical attention.

Allergy alert: Allergic reactions may occur in those sensitive to inhaling or ingesting psyllium husk.

Consult a doctor before use:
 • If you have a sudden change in bowel functions that persists for ten days or more
 • If you suffer from abdominal pain, nausea or vomiting

Discontinue and ask a doctor if - your constipation lasts seven days or more + you experience rectal bleeding

Keep out of reach of children. The product should be administered to children under adult supervision; and in case of child overdose contact a physician or a poison control center immediately.

Directions: Mix one teaspoonful of Mucilin briefly with at least one full glass (8 oz) of water or other liquid such as fruit juice or milk and drink immediately. Take another glass of fluid. Without sufficient liquid, the natural swelling of the product may cause choking. Please see **Warnings**. Do not take the product just before bedtime, or while lying down.

Adults 12yrs. & older: 1 Teaspoonful in one full glass (8 oz) of liquid, may be taken 3 times a day.

Children 6 - 11 yrs. ½ of adult dose, may be taken 3 times a day.

Under 6 yrs. Not recommended, but consult a doctor.

New Users: Start with 1 dose per day, gradually increase to 3 as necessary.

Product normally effects within 12 hrs. - 48 hrs. Due to increased fiber intake you may experience minor bloating, and change in bowel routine.

Other Information
 • One teaspoonful contains: sodium 6 mg
 • PHENYLETANOLIC ACID: CONTAINS PHENYLETANOLIC ACID (20 mg per teaspoonful)
 • Store at room temperature. Tightly close the bottle to protect from humidity
 • Contains 100% natural soluble fiber

Inactive Ingredients: Acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, FD&C Yellow No. 6, mannitol, orange flavor, sodium chloride

Questions? Call toll-free: 833-MUCILIN®

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Mucilin® is psyllium husk, consumed for centuries as a source of natural fiber for multiple health benefits.

Fiber Supplement Information

Uses - Daily fiber supplement: One serving adds 3.5 grams of natural fiber to diet.
 • **Healthy Heart†:** Soluble fiber from psyllium husk as in Mucilin™ amounts 7 gm daily when included as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease (CHD) by lowering blood cholesterol levels.† Speak to your doctor for using this product in cholesterol-lowering regimen.

Warnings: Read entire label, including Direction of Use and Warnings in Drug Facts.

Directions: Adults, 12 yrs and older: 1 Teaspoonful in 8 oz of water or another liquid, up to 3 times a day for daily fiber supplement; for 6 to 11 yrs half of adult serving; consult doctor for children under 6 yrs. Mix and drink immediately, followed by an additional glass of fluid. See mixing directions in Drug Facts.

Caution: Consuming without sufficient liquid may cause choking. If you have difficulty in swallowing do not take this product.

† Data are in saturated fat and cholesterol that include 7 grams or more of soluble fiber daily from psyllium husk, as in Mucilin. This may reduce the risk of heart disease. One adult serving of Mucilin (US FDA, CITE: 21CFR101.81) The reduced risk of heart disease is through the intermediate link of blood cholesterol. (US FDA, CITE: 21CFR101.81)

Supplement Facts

Serving Size	Amount Per Serving	% Daily Value	% Daily Value
1 Teaspoonful (5 mL)	3.5g	7%	7%
Total Fiber	3.5g	7%	7%
Dietary Fiber	3.5g	7%	7%
Total Sugars	0g	0%	0%
Total Fat	0g	0%	0%
Sodium	6mg	12%	12%
Total Protein	0g	0%	0%

Other ingredients: Acesulfame potassium, anhydrous citric acid, aspartame, colloidal silicon dioxide, FD&C Yellow No. 6, mannitol, orange flavor, sodium chloride

PHENYLETANOLIC ACID: CONTAINS PHENYLETANOLIC ACID

Precaution:

- Take it with sufficient liquid (See Direction for use)
- Do not mix in hot water
- Drink immediately, avoid if it burns into jelly when left too long before consuming
- Do not consume at bedtime
- Do not consume if you have problem swallowing, or experience abdominal pain, nausea or vomiting

NDC: 72430-003-01

Store at room temperature.

Tightly close the bottle to protect from humidity.

NDC 72430-003-01



Mucilin SF

ORANGE FLAVOR SUGAR FREE



Soluble Fiber

- Healthy Heart^{†*}
- Blood Sugar Control^{*}
- Colon Health/Bulk Laxative^{*}
- Appetite Control Between Meals^{*}



DAILY FIBER SUPPLEMENT

Mix and Drink

Manufactured Under Pharmaceutical Control^{*}
 NET WT 14.110Z (0.88 LBS) 400 g

Health Benefits in One

Healthy Heart^{†*}
 † Data are in saturated fat and cholesterol that include 7 grams or more of soluble fiber daily from psyllium husk, as in Mucilin. This may reduce the risk of heart disease. One adult serving of Mucilin powder has 3.5 grams of this soluble fiber. (US FDA, CITE: 21CFR101.81)
 The reduced risk of heart disease is through the intermediate link of blood cholesterol. (US FDA, CITE: 21CFR101.81)

Blood Sugar Control^{*}

Colon Health/Bulk Laxative^{*}

Appetite Control Between Meals^{*}

[†] US FDA, CITE: 21CFR101.81
^{*} These statements have not been evaluated by the Food and Drug Administration.
 This product is not intended to diagnose, treat, cure, or prevent any disease.

Direction for use:

- Mix one teaspoonful of Mucilin in one full glass (8 oz) of cool water, milk, fruit juice or other liquid
- Stir briskly and drink immediately
- Followed by an additional glass of water or other drinking liquid

Questions? Call toll-free: 833-MUCILIN®

Lot No.:

Mfg. Date:

Best Before:

MUCILIN SF

psyllium (ispaghula) husk powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72430-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSYLLIUM HUSK (UNII: 0SHO53407G) (PSYLLIUM HUSK - UNII:0SHO53407G)	PSYLLIUM HUSK	3.5 g in 5 g

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ASPARTAME (UNII: Z0H242BBR1)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72430-003-02	30 in 1 BOX	01/15/2020	
1		5 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:72430-003-01	400 g in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/15/2020	

Labeler - Paradigm Pharmaceuticals Inc (080044989)

Establishment

Name	Address	ID/FEI	Business Operations
BERLIN PHARMACEUTICAL INDUSTRY COMPANY LIMITED - (BRANCH)		661748158	manufacture(72430-003)

Revised: 2/2023

Paradigm Pharmaceuticals Inc