

MUCILIN- 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 Orange

Active Ingredient

Psyllium (Ispaghula) husk 2.45 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, 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

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

One sachet contains: sodium 7 mg
Store at room temperature.
Contains 100% natural soluble fiber

Inactive Ingredients

Anhydrous citric acid, colloidal silicon dioxide, dextrose anhydrous, FD&C Yellow No. 6, orange flavor, saccharin sodium, sodium benzoate, sucrose

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

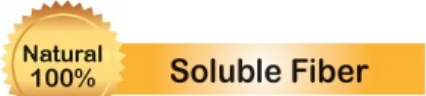
Product Label

Mucilin

ORANGE FLAVOR


Psyllium (Ispaghula) Husk 100%

Best Before




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**
Pharmaceuticals Inc.

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 Romklao Road, Klongsamprvet,
Latkrabang, Bangkok 10520, Thailand

Mucilin

ORANGE FLAVOR

Each sachet (5 g) contains:
Psyllium (Ispaghula) husk powder 2.45 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

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.

Lviva.com 

30 Sachets

Mucilin

ORANGE FLAVOR

DAILY FIBER SUPPLEMENT
Milk and Drink

LVIVA Supplement Life

NET WT 5.29 OZ (150 g)

NCC 7430-004-01

Mucilin

ORANGE FLAVOR

30 Sachets

B11112



Natural 100% Soluble Fiber

Lot No.:



DAILY FIBER SUPPLEMENT
Mix and Drink

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

Mfg. Date:

Best Before:

C0385



843197100012

MUCILIN
psyllium (ispaghula) husk powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72430-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSYLLIUM HUSK (UNII: 0SHO53407G) (PSYLLIUM HUSK - UNII:0SHO53407G)	PSYLLIUM HUSK	2.45 g in 5 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72430-004-01	30 in 1 BOX	01/15/2020	
1		5 g in 1 POUCH; Type 0: Not a Combination Product		

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(72430-004)