

ONELAX FIBER THERAPY ORIGINAL COARSE- psyllium husk powder
Akron Pharma 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.

OneLAX Fiber Therapy
100% Natural Psyllium Husk
Multihealth Dairy Fiber Supplement

Drug Facts

Active ingredient: (in each teaspoon)

Psyllium husk approximately 3.4 g

Purpose

Bulk-forming Laxative

Uses:

- for relief of occasional constipation (irregularity)
- generally produces bowel movement in 12-72 hours

Warnings:

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.

Allergy alert:

This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium.

Ask a doctor before use if you have

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

Stop use and ask a doctor if

- constipation lasts more than 7 days
- rectal bleeding occurs

These may 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 at 1-800-222-1222.

Directions:

Put one dose into an empty glass. Mix 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. Stir briskly and drink promptly. If mixture thickens, add more liquid and stir.

Adults & children 12 years & older:	1 rounded teaspoon in 8 ounces of liquid at the first sign of irregularity. Can be taken up to 3 times daily.
Children 6 - 11 yrs:	½ adult dose in 8 ounces of liquid, up to 3 times daily
Children under 6 yrs:	Consult a doctor

Bulk forming fibers like psyllium husk may affect how well other medicines work. If you are taking a prescription medicine by mouth, take this product at least 2 hours before or 2 hours after the prescribed medicine. As your body adjusts to increased fiber intake, you may experience changes in bowel habits or minor bloating.

New Users

Start with 1 serving per day; gradually increased to desired daily intake. You may initially experience changes in bowel habits or minor bloating, as your body adjusts to increased fiber intake.

Other information

- **each teaspoon contains:** potassium 35 mg; sodium 5 mg
- store at room temperature. Keep the container tightly closed to protect from humidity
- contains a 100% natural, therapeutic fiber

Inactive ingredients

citric acid, colloidal silicon dioxide, FD&C Yellow No.6, sucrose, orange flavor, sodium benzoate, sucralose.

Questions or comments ?

Call toll-free 1-877-225-6999.

Supplement Facts

<h1>Supplement Facts</h1>

Serving Size

2 rounded Tbsp(24g)

1 rounded Tbsp(12g)

Servings Per Container

About 15

About 30

Amount per Serving

%DV*

%DV*

Calories

90

45

Total Carbohydrate

23 g

8%*

12 g

4%*

Dietary Fiber

6 g

21%*

3 g

11%*

Soluble Fiber

5 g

†

2 g

†

Total sugars

0 g

†

0 g

†

Iron

1.4 mg

8%

0.7 mg

4%

Sodium

10 mg

<1%

5 mg

<1%

Potassium

70 mg

1%

35 mg

1%

*Percent daily Values(%DV) are based on a 2,000 calorie diet.

†Daily Value (DV) not established.

INGREDIENTS: citric acid, colloidal silicon dioxide, FD&C Yellow No.6, maltodextrin, orange flavor, psyllium husk, sodium benzoate, sucralose.

Notice: Put 1 dose of product into an empty glass. Mix this product with at least 8 ounces (a full glass) of liquid. Stir briskly and drink promptly. Taking without enough liquid may cause choking. Do not take if you have difficulty swallowing.

Allergy alert: This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium. Contact your doctor BEFORE USING this dietary supplement if you have recently experienced a sudden change in bowel habits persisting for 2 weeks, abdominal pain, nausea or vomiting. STOP USING this dietary supplement and ask a doctor if constipation lasts more than 7 days or rectal bleeding occurs. These may be signs of a serious condition.

New Users: Start with 1 serving per day, gradually increase to desired daily intake.

You may initially experience changes in bowel habits or minor bloating, as your body adjusts to increased fiber intake.

When used as a daily fiber supplement:

Fiber Supplement Information

Uses & Directions: For feeling less hungry between meals**

Adults & children 12 yrs, and over: Two rounded tablespoons in 8 or more ounces of liquid with meals, up to 3 times daily.

For lowering cholesterol to promote heart health[†]

Adults & children 12 yrs and over: One rounded tablespoon in 8 ounces of liquid 3 times daily

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

For maintaining healthy blood sugar levels as part of your diet**

Adults & children 12 yrs, and over: One rounded tablespoon in 8 ounces of liquid, 3 times daily. Consult your doctor before use if you are currently using medication to control your blood sugar levels.

For promoting and maintaining digestive health**

Adults & children 12 yrs, and over: One rounded tablespoon in 8 ounces of liquid up to 3 times daily for fiber supplementation. For occasional constipation and to help promote and maintain regularity. **For children under 12 yrs:** consult a doctor.

71399-6585-3

OneLAX™

Fiber Therapy

100% Natural Psyllium Husk Multi Health Daily Fiber Supplement For Regularity

Helps you feel less hungry between meals**
 Helps maintain healthy blood sugar levels as part of your diet**
 Helps lower cholesterol to promote heart health*
 Promotes digestive health**
 Gluten-Free

*Serving size varies. See DIRECTIONS on back panel for more information.
 **See back for information about soluble fiber and heart disease.

ORANGE FLAVOR
Naturally and Artificially Flavored

30 TABLESPOON† DOSES
Net Wt 13 oz (368g)

Supplement Facts

Serving Size	2 rounded Tbsp(24g)	1 rounded Tbsp(12g)
Servings Per Container	About 15	About 30
Amount per Serving		
Calories	90	45
Total Carbohydrate	23g 8%*	12g 4%*
Dietary Fiber	8g 21%*	3g 11%*
Soluble Fiber	5g †	2g †
Total sugars	18g †	8g †
Includes Added Sugars	18g 32%*	8g 16%*
Iron	1.4 mg 3%	0.7 mg 4%
Sodium	10 mg <1%	5 mg <1%
Potassium	70 mg 1%	35 mg 1%

*Percent Daily Values(%DV) are based on a 2,000 calorie diet.
 †Daily Value (DV) not established.

INGREDIENTS: citric acid, colloidal silicon dioxide, FD&C Yellow No.6, sucrose, orange flavor, psyllium husk, sodium benzoate, sucralose.

Notice: Put 1 dose of product into an empty glass. Mix this product with at least 8 ounces (a full glass) of liquid. Stir briskly and drink promptly. Taking without enough liquid may cause choking. Do not take if you have difficulty swallowing.

Allergy alert: This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium. Contact your doctor BEFORE USING this dietary supplement if you have recently experienced a sudden change in bowel habits persisting for 2 weeks, abdominal pain, nausea or vomiting. STOP USING this dietary supplement and ask a doctor if constipation lasts more than 7 days or rectal bleeding occurs. These may be signs of a serious condition.

New Users: Start with 1 serving per day, gradually increase to desired daily intake. You may initially experience changes in bowel habits or minor bloating, as your body adjusts to increased fiber intake.

When used as a daily fiber supplement:

Fiber Supplement Information

Uses & Directions: For feeling less hungry between meals**
Adults & children 12 yrs, and over: Two rounded tablespoons in 8 or more ounces of liquid with meals, up to 3 times daily.

For lowering cholesterol to promote heart health*
Adults & children 12 yrs, and over: One rounded tablespoon in 8 ounces of liquid, 3 times daily. Diets low in saturated fat and cholesterol that include 7grams of soluble fiber per day from psyllium husk, as in this product, may reduce the risk of heart disease by lowering cholesterol. One serving of this product has 2.4 grams of this soluble fiber. Consult a doctor if you are considering use of this product as a part of a cholesterol-lowering program.

For maintaining healthy blood sugar levels as part of your diet**
Adults & children 12 yrs, and over: One rounded tablespoon in 8 ounces of liquid, 3 times daily. Consult your doctor before use if you are currently using medication to control your blood sugar levels.

For promoting and maintaining digestive health**
Adults & children 12 yrs, and over: One rounded tablespoon in 8 ounces of liquid up to 3 times daily for fiber supplementation. For occasional constipation and to help promote and maintain regularity. **For children under 12 yrs:** consult a doctor.

When used as a therapy for regularity:

Drug Facts

Active Ingredient (in each 1 rounded Tbsp (12g))
 Psyllium husk approximately 3.4 g

Purpose
 Bulk-forming laxative

Uses: for relief of occasional constipation (irregularity)
 ■ generally produces bowel movement in 12-72 hours

Warnings:
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.

Allergy alert: This product may cause allergic reaction in people sensitive to inhaled or ingested psyllium.

Ask a doctor before use if you have ■ a sudden change in bowel habits persisting for 2 weeks
 ■ abdominal pain, nausea or vomiting

Stop use and ask a doctor if ■ constipation lasts more than 7 days ■ rectal bleeding occurs
 These may 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 at 1-800-222-1222.

Directions: Put one dose into an empty glass. Mix 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. Stir briskly and drink promptly. If mixture thickens, add more liquid and stir.

Adults & children 12 years & older: 1 rounded tablespoon in 8 ounces of liquid at the first sign of irregularity. Can be taken up to 3 times daily.

Children 6-11 yrs: 1/2 adult dose in 8 ounces of liquid, up to 3 times daily

Children under 6 yrs: Consult a doctor

Bulk-forming fibers like psyllium husk may affect how well other medicines work. 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 serving per day; gradually increased to desired daily intake. You may initially experience changes in bowel habits or minor bloating, as your body adjusts to increased fiber intake.

Other information:
 ■ each tablespoon contains: potassium 35 mg; sodium 5 mg
 ■ store below 86° F (30° C), keep the container tightly closed to protect from humidity
 ■ contains a 100% natural, therapeutic fiber

Inactive ingredients:
 citric acid, colloidal silicon dioxide, FD&C Yellow No.6, sucrose, orange flavor, sodium benzoate, sucralose.

Questions or comments? Call toll-free 1-877-225-6999.

TAMPER EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS BROKEN OR MISSING

**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. GLUTEN-FREE may contain trace amounts less than 20 ppm. If you have specific dietary needs, you should consult your doctor before consuming this product. This product has a low glycemic index, a measure of the effect of dietary carbohydrates on blood sugar levels.

Lot No: _____
 Exp Date: _____

Rev.:02/22

Akron Pharma
 Manufactured for:
 Akron Pharma Inc.,
 Fairfield, NJ-07004
 www.akronpharma.com
 FSSAI Lic No: 1001170200338

ONELAX FIBER THERAPY ORIGINAL COARSE

psyllium husk powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-6585
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 7 g	

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
Sucrose (UNII: C151H8M554)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-6585-3	368 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2023	

Labeler - Akron Pharma Inc. (067878881)

Revised: 3/2023

Akron Pharma Inc.