

KONSYL ORANGE FLAVOR PSYLLIUM FIBER - SMOOTH TEXTURE- psyllium husk granule

Konsyl 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.

KONSYL Orange Flavor Psyllium Fiber - Smooth Texture

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Active Ingredient (in each tablespoon)

Psyllium Hydrophilic Mucilloid 3.4 g

Purpose

Laxative

Uses

For relief of occasional constipation and to induce regularity. This product generally produces bowel movement within 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.

Do not use

- when abdominal pain, nausea or vomiting are present unless directed by a doctor
- If constipation lasts more than seven days
- if you have difficulty swallowing

Ask a doctor before use if you have

- noticed a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if

- you experience rectal bleeding or fail to have a bowel movement, as 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.

Directions

Mix this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough fluid may cause choking. See choking warning.

adults and children 12 years and older	one teaspoon 1 to 3 times daily
children 6 to under 12 years of age	1/2 teaspoon 1 to 3 times daily
children under 6 years of age	consult a doctor.

Other Information

- each tablespoon contains Potassium 25mg, Sodium 5mg
- laxatives, including bulk fibers, may affect how other medicines work, wait 1-2 hours before or after taking other medicines
- tamper-evident bottle mouth sealed for your protection
- do not use if imprinted inner seal is broken or missing
- do not discard Konsyl into any plumbing system
- store below 86 degrees F (30 degrees C)
- keep container tightly closed-protect from excessive moisture
- can be taken before or after meals, mornings or evenings

Inactive Ingredients

Citric Acid, D&C Yellow No. 10, FD&C Yellow No. 6, Natural and Artificial Orange Flavor, Sugar

Questions or Comments?

- 1-800-356-6795 8:30 a.m. to 5 p.m. ET.

Representative Labeling

NDC 0224-1852-06

Drug Facts	
Active ingredient (in each tablespoon) Psyllium Hydrophilic Mucilloid 3.4g	Purpose Laxative
Uses For relief of occasional constipation and to induce regularity. This product generally produces bowel movements within 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.	
Do not use	
<ul style="list-style-type: none"> when abdominal pain, nausea or vomiting are present unless directed by a doctor if constipation lasts more than seven days if you have difficulty swallowing 	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> noticed a sudden change in bowel habits that persists over a period of 2 weeks 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> you experience rectal bleeding or fail to have a bowel movement, as 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.	
Directions Mix this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough fluid may cause choking. See choking warning.	
adults and children 12 years and older	one tablespoon 1 to 3 times daily
children 6 to under 12 years of age	1/2 tablespoon 1 to 3 times daily
children under 6 years of age	consult a doctor*
Other information	
<ul style="list-style-type: none"> each tablespoon contains Potassium 25mg, Sodium 5mg laxatives, including bulk fibers, may affect how other medicines work, wait 1-2 hours before or after taking other medicines tamper-evident bottle mouth sealed for your protection do not use if imprinted inner seal is broken or missing do not discard Konsyl into any plumbing system store below 86° F (30° C) keep container tightly closed-protect from excessive moisture can be taken before or after meals, mornings or evenings 	
Inactive ingredients Citric Acid, FD&C Yellow No. 6, Natural and Artificial Flavor, Sugar	
Questions or Comments? 1-800-356-6796 8:30 a.m. to 5 p.m. ET.	

*For lowering cholesterol to promote heart health. Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium husk as in Konsyl Orange may reduce the risk of heart disease by lowering cholesterol. One adult dose of Konsyl Orange has 2 grams of this soluble fiber.



ORANGE FLAVOR

naturally and artificially flavored

PSYLLIUM FIBER

LAXATIVE / SUPPLEMENT

For relief of occasional constipation and irregularity

Naturally Sweetened

45 Doses

Smooth Texture

Gluten Free

Helps Lower Cholesterol To Support Heart Health*



NET WEIGHT 538g (19oz)

Supplement Facts	
Serving Size: 1 tablespoon (12g) Servings Per Container 45	
Amount Per Serving	% Daily Value
Calories 45	
Total Carbohydrate 11g	4%*
Dietary Fiber 3g	11%*
Soluble Fiber 2g	†
Insoluble Fiber 1g	†
Sugars 7g	†
Iron 1g	6%
Sodium 5mg	<1%

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

Ingredients: Sugar, Psyllium Hydrophilic Mucilloid (Husk), Citric Acid, Natural And Artificial Flavor, FD&C Yellow No. 6.

Manufactured By: Konsyl Pharmaceuticals, Inc. Easton, MD 21801 www.konsyl.com ©Konsyl Pharmaceuticals, Inc.

Dosage: Adults and children 12 years and over: One tablespoon 1 to 3 times daily. Children 6 to under 12 years of age: 1/2 tablespoon 1 to 3 times daily. Follow with additional fluid to aid product action, before or after meals, mornings or evenings. Children under 6 years of age: consult a doctor. **Notice:** This product should be taken with at least a full glass of liquid. 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. **Warnings:** Read entire label, including warnings in Drug Facts. **Allergy Alert:** Inhaled or ingested psyllium powder may cause an allergic reaction in people sensitive to psyllium.

33792 0514



Package Labeling: 0224-1852-80

Drug Facts	
Active ingredient (in each tablespoon) Psyllium Hydrophilic Mucilloid 3.4g	Purpose Bulk-forming laxative
Use For relief of occasional constipation and to induce regularity. This product generally produces bowel movements within 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.	
Do not use	
<ul style="list-style-type: none"> when abdominal pain, nausea or vomiting are present unless directed by a doctor if constipation lasts more than seven days if you have difficulty swallowing 	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> noticed a sudden change in bowel habits that persists over a period of 2 weeks 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> you experience rectal bleeding or fail to have a bowel movement, as 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.	
Directions Mix this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without enough fluid may cause choking. See choking warning.	
adults and children 12 years and older	one tablespoon 1 to 3 times daily
children 6 to under 12 years of age	1/2 tablespoon 1 to 3 times daily
children under 6 years of age	consult a doctor
Other information	
<ul style="list-style-type: none"> each tablespoon contains Potassium 25mg, Sodium 5mg laxatives, including bulk fibers, may affect how other medicines work, wait 1-2 hours before or after taking other medicines tamper-evident bottle mouth sealed for your protection do not use if imprinted inner seal is broken or missing do not discard Konsyl into any plumbing system store below 86° F (30° C) keep container tightly closed-protect from excessive moisture can be taken before or after meals, mornings or evenings 	
Inactive ingredients Citric Acid, D&C Yellow No. 10, FD&C Yellow No. 6, Natural and Artificial Orange Flavor, Sugar	
Questions or Comments? +1-410-822-5192 8:30 a.m. to 5 p.m. ET.	

*For lowering cholesterol to promote heart health. Diets low in saturated fat and cholesterol that include 7 grams of soluble fiber per day from psyllium husk as in Konsyl Orange may reduce the risk of heart disease by lowering cholesterol. One adult dose of Konsyl Orange has 2 grams of this soluble fiber.

NDC 0224-1852-80

NEW LOOK
Same trusted formula!

NATURALLY SWEETENED

Konsyl

ORANGE FLAVOR DAILY FIBER

100% Natural Psyllium

- ✓ Helps support digestive health
- ✓ Helps support healthy weight*
- ✓ Helps lower cholesterol to promote heart health**



GLUTEN FREE



PAREVE



Naturally and Artificially Flavored



NET WEIGHT 19 oz (538g) POWDER LAXATIVE / FIBER SUPPLEMENT

Supplement Facts	
Serving Size: 1 tablespoon (12g) Servings Per Container 45	
Amount Per Serving	% Daily Value
Calories 45	
Total Carbohydrate 11g	4%*
Dietary Fiber 3g	11%*
Soluble Fiber 2g	†
Insoluble Fiber 1g	†
Sugars 7g	†
Iron 1g	6%
Sodium 5mg	<1%

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

Ingredients: Sugar, Psyllium Hydrophilic Mucilloid (Husk), Citric Acid, Natural and Artificial Orange Flavor, D&C Yellow No. 10, FD&C Yellow No. 6.

Manufactured For: Konsyl Pharmaceuticals, Inc. Easton, MD 21801 www.konsyl.com ©Konsyl Pharmaceuticals, Inc.

Dosage: Adults and children 12 years and over: One tablespoon 1 to 3 times daily. Children 6 to under 12 years of age: 1/2 tablespoon 1 to 3 times daily. Follow with additional fluid to aid product action, before or after meals, mornings or evenings. Children under 6 years of age: consult a doctor. **Notice:** This product should be taken with at least a full glass of liquid. 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. **WARNING:** This product can expose you to chemicals including lead, which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov. Read entire label, including warnings in Drug Facts. **Allergy Alert:** Inhaled or ingested psyllium powder may cause an allergic reaction in people sensitive to psyllium.

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

34758 0619



Package Labeling: 0224-1852-81



KONSYL ORANGE FLAVOR PSYLLIUM FIBER - SMOOTH TEXTURE psyllium husk granule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0224-1852
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0224-1852-06	538 g in 1 CANISTER; Type 0: Not a Combination Product	03/31/2011	04/01/2020
2	NDC:0224-1852-80	538 g in 1 CANISTER; Type 0: Not a Combination Product	03/31/2011	05/01/2024
3	NDC:0224-1852-81	30 in 1 BOX	03/31/2011	08/01/2022

3		12 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:0224-1852-13	30 in 1 BOX	03/31/2011	01/01/2020
4		12 g in 1 PACKET; 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	03/31/2011	05/01/2024

Labeler - Konsyl Pharmaceuticals, Inc. (102463866)

Registrant - Konsyl Pharmaceuticals, Inc. (102463866)

Revised: 12/2021

Konsyl Pharmaceuticals, Inc.