

KONSYL SUGAR FREE ORANGE WITH STEVIA- psyllium husk powder
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 Sugar free Orange With Stevia

Drug Facts

Active Ingredient (in each teaspoon)

Psyllium Hydrophilic Mucilloid 3.5g

Purpose

Laxative

Use

For relief of occasional constipation and aid in 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

- 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 5.8g dose contains **Potassium** 35mg
- 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 use discard konsyl inot 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, Maltodextrin, Natural and Artificial Orange Flavor, Rebaudioside A, Silicon Dioxide.

Questions or Comments?

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

Konsyl Sugar free Orange With Stevia, 450g (0224-1884-81)

NDC 0224-1884-81

Drug Facts

Active Ingredient (in each teaspoon)
 Psyllium Hydrophilic Mucliloid 3.5g

Purpose
 Laxative

Use For relief of occasional constipation and to aid in regularity. This product generally produces bowel movements within 12-72 hours.

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

Other Information

- each 5.8g dose contains Potassium 35mg
- 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, Maltodextrin, Natural and Artificial Orange Flavor, Rebamucoside A, Silicon Dioxide.

Questions or Comments? 1-800-356-6795 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 Sugar-Free may reduce the risk of heart disease by lowering cholesterol. One adult dose of KONSYL Orange Sugar-Free has 2 grams of this soluble fiber.

KONSYL

SUGAR FREE

SUGAR FREE ORANGE

DAILY FIBER

100% Natural Psyllium

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

Naturally and Artificially Flavored

77 DOSES

NET WEIGHT 15.9oz (450g)

POWDER LAXATIVE / SUPPLEMENT

Supplement Facts

Serving Size: 1 teaspoon (5.8g)
 Servings Per Container 77

Amount Per Serving	% Daily Value
Calories 20	
Total Carbohydrate 5g	2%*
Dietary Fiber 3g	12%*
Soluble Fiber 2g	†
Insoluble Fiber less than 1g	†

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

Ingredients: Psyllium Hydrophilic Mucliloid (Husks), Maltodextrin, Natural and Artificial Orange Flavor, Citric Acid, Rebamucoside A, FD&C Yellow No. 6.

Manufactured For: Konsyl Pharmaceuticals, Inc. Easton, MD 21601
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Dosage: Adults and children 12 years and over: One teaspoon 1 to 3 times daily. Children 6 to under 12 years of age: 1/2 teaspoon 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.



34785

Package Labeling: 0224-1884-82

Drug Facts

Active Ingredient (in each packet)
 Psyllium Hydrophilic Mucliloid 3.5g

Purpose
 Bulk-forming laxative

Use For relief of occasional constipation and to aid in 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

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- if constipation lasts more than seven days
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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.

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Starting out with Konsyl?

When using this product, physicians recommend a gradual increase in dietary fiber. If minor gas or bloating occurs, begin with a half-dose of KONSYL and slowly increase the dose over several days. Always follow with 8 oz. of fluid.

Supplement Facts

Serving Size: 1 packet (5.8g)
 Servings Per Carton 30

Amount Per Serving	% Daily Value
Calories 20	
Total Carbohydrate 5g	2%*
Dietary Fiber 3g	12%*
Soluble Fiber 2g	†
Insoluble Fiber less than 1mg	†

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

Ingredients: Psyllium Hydrophilic Mucliloid (Husks), Maltodextrin, Natural and Artificial Orange Flavor, Citric Acid, Rebamucoside A, FD&C Yellow No. 6.

Dosage: Adults and children 12 years and over: One packet 1 to 3 times daily. Children 6 to under 12 years of age: 1/2 packet 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.

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Manufactured For: Konsyl Pharmaceuticals, Inc. 800 Industrial Park Road Easton, MD 21601 www.konsyl.com

©Konsyl Pharmaceuticals, Inc. 0224-1884-82 2

Drug Facts (cont'd)

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 packet 1 to 3 times daily
 children 6 to under 12 years of age | 1/2 packet 1 to 3 times daily
 children under 6 years of age | consult a doctor

Other Information

- each 5.8g dose contains Potassium 35mg
- laxatives, including bulk fibers, may affect how other medicines work, wait 1-2 hours before or after taking other medicines
- tamper-evident packaging, do not use if opened or damaged
- do not discard Konsyl into any plumbing system
- store below 86° F (30° C)
- can be taken before or after meals, mornings or evenings

Inactive Ingredients Citric Acid, FD&C Yellow No. 6, Maltodextrin, Natural and Artificial Orange Flavor, Rebamucoside A, Silicon Dioxide

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KONSYL SUGAR FREE ORANGE WITH STEVIA

psyllium husk powder

Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	TOPICAL	NDC:0224-1884

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSYLLIUM HUSK (UNII: 0SHO53407G) (PSYLLIUM HUSK - UNII:0SHO53407G)	PSYLLIUM HUSK	3.5 g in 5.8 g

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
REBAUDIOSIDE A (UNII: B3FUD0528F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0224-1884-81	77 in 1 CARTON	10/01/2018	06/01/2024
1		5.8 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:0224-1884-82	30 in 1 CARTON	10/01/2018	08/01/2022
2		5.8 g in 1 PACKAGE; 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	10/01/2018	06/01/2024

Labeler - Konsyl Pharmaceuticals, Inc. (102463866)

Revised: 12/2021

Konsyl Pharmaceuticals, Inc.