# KONSYL ORIGINAL FORMULA PSYLLIUM FIBER- 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.

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# Konsyl Original Formula Psyllium Fiber

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# Active Ingredients (in each teaspoon)

Psyllium Hydrophilic Mucilloid 6g

## 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

- 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

#### **Other Information**

- each 6g dose contains: Potassium 50mg
- laxatives, including bulk fibers, may affect how other 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**

none

#### **Questions or comments?**

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

#### **Package Labeling**



NET WEIGHT 450g (15.9oz)

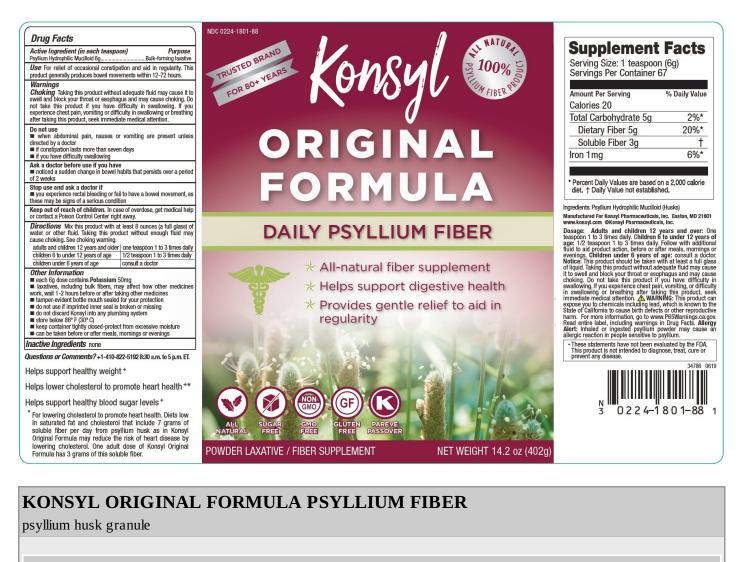
#### Package Labeling: 0224-1801-80



#### Package Labeling: 0224-1801-84



Package Labeling: 0224-1801-88



Product	Information
PIUUULL	

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0224-1801
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
PSYLLIUM HUSK (UNII: 0SHO53407G) (PSYLLIUM HUSK - UNII:0SHO53407G)	PS YLLIUM HUS K	6g in 6g

#### Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0224-1801-84	30 in 1 BOX	0 3/3 1/20 11	
1		6 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0224-1801-35	30 in 1 BOX	0 3/3 1/20 11	0 3/0 1/20 20
2		6 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0224-1801-07	450 g in 1 CANISTER; Type 0: Not a Combination Product	0 3/3 1/20 11	04/01/2020
4	NDC:0224-1801-81	450 g in 1 CANISTER; Type 0: Not a Combination Product	0 3/3 1/20 11	
5	NDC:0224-1801-06	300 g in 1 CANISTER; Type 0: Not a Combination Product	0 3/3 1/20 11	04/01/2020
6	NDC:0224-1801-80	300 g in 1 CANISTER; Type 0: Not a Combination Product	0 3/3 1/20 11	
7	NDC:0224-1801-88	402 g in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	03/31/2011		
0 0 0		5	Marketing Ent	

Labeler - Konsyl Pharmaceuticals, Inc. (102463866)

# Registrant - Konsyl Pharmaceuticals, Inc. (102463866)

Revised: 10/2019

Konsyl Pharmaceuticals, Inc.