LEADER FIBER- psyllium husk capsule Cardinal Health

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.

Leader 100 Fiber Capsules

Drug Facts

Active ingredient (in each capsule)

Psyllium husk approx. 0.52 g

Purpose

fiber laxative

Uses

effective in treating occasional constipation and restoring regularity

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

Ask a doctor or pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

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.

Directions

- take at the first sign of irregularity
- take 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.
- **adults and children 12 years of age and over:** take 5 capsules with at least 8 oz. of liquid. Swallow capsules one at a time. May repeat dose up to 3 times a day.
- children 12 years and under: ask a doctor

Other information

- do not use if printed inner seal is torn or missing
- store at room temperature tightly closed to protect from humidity
- contains a 100% natural, therapeutic fiber
- each capsule contains potassium 5 mg

Inactive ingredients

blue 1, caramel color, gelatin, polysorbate 80, shellac, sodium lauryl sulfate, titanium dioxide.

Distributed By: Cardinal Health

Dublin OH 43017

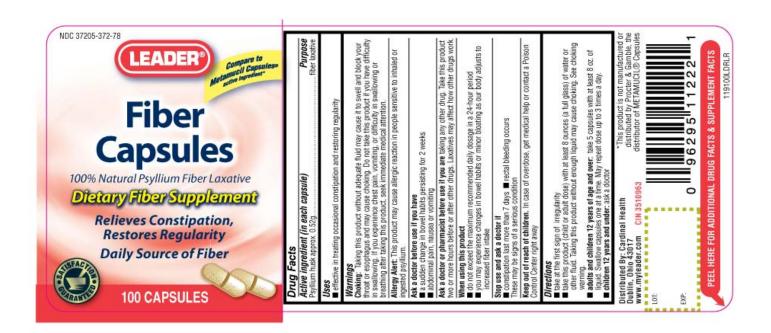
PRINCIPAL DISPLAY PANEL - 100 Capsules Label

NDC 37205-372-78

Leader Fiber Capsules

100% Natural Psyllium Fiber Laxative Relieves Constipation/ Restores regularity

100 CAPSULES





Leader Fiber Capsules

LEADER FIBER psyllium husk capsule

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:37205-372 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Psyllium Husk (UNII: 0SHO53407G) (Psyllium Husk - UNII:0SHO53407G)	Psyllium Husk	0.52 g	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
CARAMEL (UNII: T9D99G2B1R)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)		
SHELLAC (UNII: 46 N10 7B71O)		
SODIUM LAURYL SULFATE (UNII: 368 GB5141J)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	BROWN	Score	no score
Shape	CAPSULE	Size	21mm
Flavor		Imprint Code	FC119
Contains			

ı	Packaging					
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:37205-372-78	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2019			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/16/2019	

Labeler - Cardinal Health (097537435)

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