## LEADER FIBER- calcium polycarbophil tablet, film coated 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.

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#### **Leader Fiber Caplets Drug Facts**

#### Active ingredient (in each caplet)

Calcium polycarbophil 625 mg

#### **Purpose**

Bulk-forming laxative

#### Uses

relieves:

- constipation
- helps restore & maintain regularity
- promotes normal function of the bowel

#### Warnings

#### Do not use if

- you have abdominal pain, nausea or vomiting
- you have difficulty in swallowing
- you have noticed a sudden change in bowel habits that persists over a period of 2 weeks

## Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking.

#### Stop use and ask a doctor if

- you experience chest pain, abdominal pain, nausea, vomiting, difficulty in breathing or swallowing
- vou fail to have a bowel movement after use
- rectal bleeding occurs
- symptoms persist more than 1 week

**Drug interaction precaution:** Contains calcium. If you are taking any form of tetracycline antibiotic, this product should be taken 1 hour before or 2 hours after you have taken the antibiotic

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- take this product (child or adult dose) with a full glass of water (8oz)
- daily maximum 4 doses
- dosage may vary according to diet, exercise, previous laxative use or severity of constipation
- continued use for 1 to 3 days is normally required to provide full benefit

adults and children 12 years of age and over	2 caplets once a day	up to 4 times a day
children under 12 years	consult a physician	

#### Other information

- each caplet contains: calcium 122 mg
- do not use if printed seal under cap is torn or missing
- store at room temperature
- protect contents from moisture

#### **Inactive ingredients**

calcium carbonate, caramel, crospovidone, hypromellose, maltodextrin, microcrystalline cellulose, magnesium stearate, methylcellulose, polyethylene glycol, silicon dioxide, sodium lauryl sulfate

#### **Principal Display Panel**

NDC 30205-213-75

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available

Fiber Caplets

Calcium Polycarbophil 625 mg

Fiber Laxative

Gentle Relief of Constipation

Won't Cause Gas or Bloating

Compare to Fibercon® active ingredient

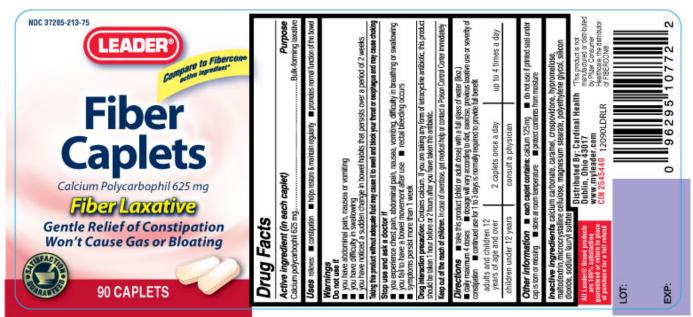
CIN 2545440

#### Distributed By:

Cardinal Health

Dublin Ohio 43017

www.myleader.com



#### Leader Fiber Caplets Label

#### LEADER FIBER

**Product Information** 

calcium polycarbophil tablet, film coated

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-213

Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength CALCIUM POLYCARBOPHIL (UNII: 8 F0 49 NKY49) (POLYCARBOPHIL UNII: W25LM17A4W) CALCIUM POLYCARBOPHIL 625 mg

Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)		
CARAMEL (UNII: T9D99G2B1R)		
CROSPO VIDO NE (15 MPA.S AT 5%) (UNII: 68401960 MK)		
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYETHYLENE GLYCOL 200 (UNII: R95B8J264J)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		

P	Product Characteristics			
C	olor	BROWN (light)	Score	2 pieces

Shape	CAPSULE (caplet)	Size	19 mm
Flavor		Imprint Code	RP120
Contains			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:37205-213-75	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/19/2019	

### Labeler - Cardinal Health (097537435)

Revised: 2/2021 Cardinal Health