

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.

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
- you 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

NDC 37205-213-75

LEADER®

Compare to Fibercon® active ingredient*

Fiber Caplets

Calcium Polycarbophil 625 mg

Fiber Laxative

Gentle Relief of Constipation
Won't Cause Gas or Bloating

90 CAPLETS

Drug Facts

Active ingredient (in each caplet)
Calcium polycarbophil 625 mg

Purpose
Bulk-forming laxative

Uses relieves: ■ constipation ■ helps restore & maintain regularity ■ prevents 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
 ■ you fail to have a bowel movement after use ■ rectal bleeding occurs
 ■ symptoms persist more than 1 week

Drug interaction precautions: 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 the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions ■ take this product (tablet or adult dose) with a full glass of water (8oz.)
 ■ daily maximum 4 doses ■ dosage will vary according to use, 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 125mg ■ do not use if puffed seal under cap is torn or missing ■ store at room temperature ■ protect contents from moisture

Inactive ingredients: calcium carbonate, caramel, croscollidone, hydroxymethylcellulose, microcrystalline cellulose, magnesium stearate, polyethylene glycol, silicon dioxide, sodium lauryl sulfate

Distributed By: Cardinal Health
 Dublin, Ohio 43017
 www.leader.com
 CIN 2949440 12090LDRLR

*The product is not manufactured or distributed by Pfizer Consumer Healthcare, the distributor of FIBERCON®.

All Leader® Brand products guaranteed to return to place of purchase for a full refund

LOT: _____ EXP: _____

0 96295 10772 2

Leader Fiber Caplets Label

LEADER FIBER

calcium polycarbophil tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-213
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49) (POLYCARBOPHIL - UNII:W25LM17A4W)	CALCIUM POLYCARBOPHIL	625 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CARAMEL (UNII: T9D99G2B1R)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
HYPROMELLOSE 2208 (100 MPAS) (UNII: B1QE5P712K)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 200 (UNII: R95B8J264J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	BROWN (light)	Score	2 pieces
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Shape	CAPSULE (caplet)	Size	19 mm
Flavor		Imprint Code	RP120
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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