

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

**State of Florida DOH Central Pharmacy**

*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
- 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
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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

**PACKAGE LABEL**

**Distributed By:**

Cardinal Health  
 Dublin Ohio 43017  
 www.myleader.com

This Product was Repackaged By:

**State of Florida DOH Central Pharmacy**  
 104-2 Hamilton Park Drive  
 Tallahassee, FL 32304  
 USA

Label Image for **53808-0963**  
**625mg**



<b>LEADER FIBER</b>			
calcium polycarbophil tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53808-0963(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 (UNII: 68401960MK)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 200 (UNII: R95B8J264J)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0963-1	30 in 1 BLISTER PACK		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	01/01/2014	

**Labeler** - State of Florida DOH Central Pharmacy (829348114)

### Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-0963)