

**FIBER LAXATIVE- calcium polycarbophil tablet**  
**CARDINAL HEALTH 110, LLC. DBA LEADER**

*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 Laxative**

**WARNING: Consuming this product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov/food](http://www.P65Warnings.ca.gov/food).**

**ACTIVE INGREDIENT (in each caplet)**

Calcium polycarbophil 625 mg equivalent to 500 mg polycarbophil

**PURPOSE**

Bulk-forming laxative

**USE(S)**

- relieves occasional constipation
- this product generally produces bowel movement in 12 to 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.

**ASK A DOCTOR BEFORE USE IF YOU HAVE**

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

**ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU ARE**

taking any other drug. Take this product 2 or more hours before or after other drugs. All laxatives may affect how other drugs work.

**WHEN USING THIS PRODUCT**

- do not use for more than 7 days unless directed by a doctor
- do not take more than 8 caplets in a 24 hour period unless directed by a doctor

### **STOP USE AND ASK DOCTOR IF**

- you experience chest pain, abdominal pain, nausea, vomiting, difficulty in breathing or swallowing
- you fail to have a bowel movement after use or have rectal bleeding. These could be signs of a serious condition.

### **KEEP OUT OF REACH OF CHILDREN**

In case of over dose, get medical help or contact a Poison Control Center immediately.

### **DIRECTIONS**

- take this product (child or adult dose) with a full glass of water (8oz.) or other fluid. Taking this product without enough liquid may cause choking. See choking warning.
- dosage will 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 and over	2 caplets, 1 to 4 times a day
children under 12 years	ask a doctor

### **OTHER INFORMATION**

- **each caplet contains:** calcium 135 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, colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium lauryl sulfate.



## Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	

## Product Characteristics

<b>Color</b>	WHITE (Off white)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	G147
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0432-1	250 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	07/24/2019	

**Labeler** - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

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