

FIBER LAXATIVE- calcium polycarbophil tablet, film coated
Geri-Care Pharmaceutical Corp

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.

gc 449(459)

Active ingredient (in each caplet)

Calcium Polycarbophil 625 mg
(equivalent to 500 mg polycarbophil)

Purpose

Bulk-forming laxative

Uses

- relieves occasional constipation
- promotes regularity
- this product generally produces a 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
- 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 a doctor if rectal bleeding occurs or if you fail to have a bowel movement after use of this or any other laxative. These could 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 each dose of this product 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.

- This laxative works naturally so continued use for one to three days is normally required to provide full benefit. Dosage may vary according to diet, exercise, previous laxative use or severity of constipation.

adults and children 12 years of age and older	Starting dose: 2 caplets once a day Maximum dose: 2 caplets four times a day or as directed by a doctor
children under 12 years of age	consult a doctor

Other information

- **each caplet contains:** calcium 138 mg
- store at controlled room temperature, 68°F-77°F (20°C-25°C)
- protect contents from moisture
- for institutional use only

Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

Inactive ingredients

caramel, cellulose, crospovidone, hypromellose, magnesium silicate, magnesium stearate, mineral oil, PEG, silica, sodium lauryl sulfate, stearic acid. May also contain calcium carbonate, croscarmellose sodium, maltodextrin, talc.

Package Label

<p>Drug Facts</p> <p>Active ingredient (in each caplet) Purpose Calcium Polycarbophil 625 mg (equivalent to 500 mg polycarbophil).....Bulk-forming laxative</p> <p>Uses • relieves occasional constipation • promotes regularity • this product generally produces a bowel movement in 12 to 72 hours</p> <p>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 • 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 a doctor if rectal bleeding occurs or if you fail to have a bowel movement after use of this or any other laxative. These could 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.</p>	 <p>NDC 57896-459-09</p> <p>Fiber Laxative Calcium Polycarbophil</p> <ul style="list-style-type: none"> • Relieves Constipation • Promotes Regularity <p>Compare to active ingredient in FiberCon®</p> <p>90 Caplets • 625 mg Each</p>	<p>Directions • take each dose of this product 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. • This laxative works naturally so continued use for one to three days is normally required to provide full benefit. Dosage may vary according to diet, exercise, previous laxative use or severity of constipation.</p> <table border="1" style="width: 100%;"> <tr> <td>adults and children 12 years of age and older</td> <td>Starting dose: 2 caplets once a day Maximum dose: 2 caplets four times a day or as directed by a doctor</td> </tr> <tr> <td>children under 12 years of age</td> <td>consult a doctor</td> </tr> </table> <p>Other information • each caplet contains: calcium 138 mg • store at controlled room temperature, 68°F-77°F (20°C-25°C) • protect contents from moisture • for institutional use only Tamper Evident: Do not use if imprinted seal under cap is missing or broken.</p> <p>Inactive ingredients: caramel, cellulose, crospovidone, hypromellose, magnesium silicate, magnesium stearate, mineral oil, PEG, silica, sodium lauryl sulfate, stearic acid. May also contain calcium carbonate, croscarmellose sodium, maltodextrin, talc.</p> <p><small>*This product is not manufactured or distributed by the owner of the registered trademark FIBERCON®. Dist. by: Geri-Care Pharmaceuticals Corp., 1650 63rd St., Brooklyn, NY 11204 REV 1118RZC</small></p>	adults and children 12 years of age and older	Starting dose: 2 caplets once a day Maximum dose: 2 caplets four times a day or as directed by a doctor	children under 12 years of age	consult a doctor
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FIBER LAXATIVE			
calcium polycarbophil tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-459
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
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
CARAMEL (UNII: T9D99G2B1R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	white (Off white to cream)	Score	2 pieces
Shape	OVAL (Caplet)	Size	19mm
Flavor		Imprint Code	CPC;339
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-459-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/01/2004	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)