CALCIUM POLYCARBOPHIL- calcium polycarbophil tablet, film coated
SHANDONG XINHUA PHARMACEUTICAL CO., LTD.

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.

Fiber Caplets
Calcium polycarbophil 625 mg

Drug Facts

Active ingredient (in each caplet)

Calcium polycarbophil 625 mg (equivalent to polycarbophil 500 mg)

Purpose

Bulk-forming laxative

Uses

relieves occasional constipation (irregularity)

generally produces bowel movement in 12 to 72 hours

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 two or more hours before or after other drugs. 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

- 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 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.) or other fluid. Taking this product without enough liquid my 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 over 12 years	2 caplets, 1 to 4 times per day
children under 12 years	ask a doctor

Other information

- **each caplet contains:** calcium 140 mg

- do not use if printed seal under cap is torn or missing
- store in a dry place at 15° – 30°C (59° – 86°F)
- protect contents from moisture

Caramel, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium lauryl sulfate

Questions or comments?

Call **1-844-374-0016** weekdays 9 AM to 5 PM EST

Fiber Caplets

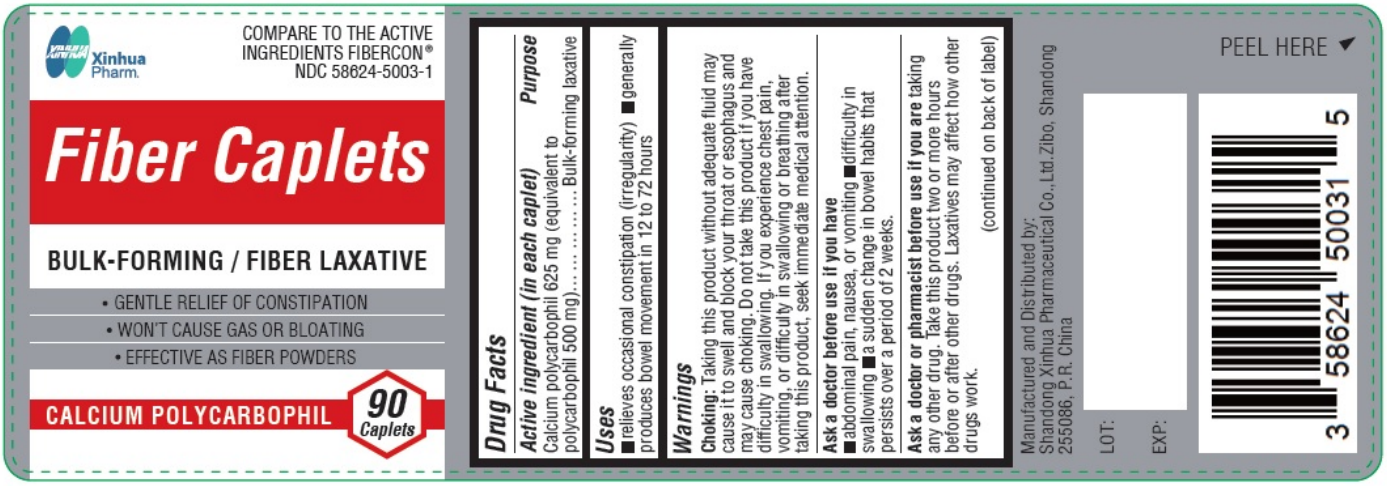
Compare to the active ingredient in FiberCon ®

BULK-FORMING / FIBER LAXATIVE

- GENTLE RELIEF OF CONSTIPATION
- WON’T CAUSE GAS OR BLOATING
- EFFECTIVE AS FIBER POWDERS

Manufactured and Distributed by: Shandong Xinhua Pharmaceutical Co., Ltd. Zibo, Shandong 255086, P.R. China

90 Caplets



CALCIUM POLYCARBOPHIL

calcium polycarbophil tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58624-5003
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**
CARAMEL (UNII: T9D99G2B1R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CROSPOVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white (off white)	**Score**	2 pieces
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	XH;C1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58624-5003-1	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/12/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/12/2023	

Labeler - SHANDONG XINHUA PHARMACEUTICAL CO., LTD. (653915728)

Registrant - SHANDONG XINHUA PHARMACEUTICAL CO., LTD. (554507599)

Establishment

Name	Address	ID/FEI	Business Operations
Shandong Xinhua Pharmaceutical Co., Ltd.		554507599	manufacture(58624-5003)

Revised: 4/2023 SHANDONG XINHUA PHARMACEUTICAL CO., LTD.