

FIBER TABS- calcium polycarbophil tablet, film coated

Major Pharmaceuticals

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.

0339-Major

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Calcium polycarbophil 625 mg equivalent to 500 mg polycarbophil

PURPOSE

Bulk-forming fiber laxative

USES

- relieves occasional constipation to help restore and maintain regularity
- this product generally produces bowel movement in 12 to 72 hours

Choking Warning: 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 tablets 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 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). Do not take more than 4 doses in 24 hours

- **adults & children over 12 years of age:** take 2 tablets 1 to 4 times a day

- **children under 12 years of age:** consult a physician

OTHER INFORMATION

- each tablet contains: **calcium 140 mg/tablet**
- store at room temperature, USP
- protect from moisture
- do not use if imprinted safety seal under cap is broken or missing

caramel, crospovidone, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, silica, sodium lauryl sulfate and stearic acid

QUESTIONS OR COMMENTS?

1-800-616-2471

*This product is not manufactured or distributed by Pfizer, owner of the registered trademark FiberCon®

Distributed by: **MAJOR® PHARMACEUTICALS**

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Livonia, MI 48152

PRINCIPAL DISPLAY PANEL

NDC 0904-2500-91

MAJOR

Fiber-Tabs™

Bulk-Forming Laxative

Calcium Polycarbophil 625 mg

Fiber Therapy for Regularity

*Compare to the active ingredient in FiberCon®

90 Tablets

Be-Order No.
700255

POTENCY
GUARANTEED

MAJOR

NOC 0904-2500-91

Fiber-Tabs™
Bulk-Forming Laxative
Calcium Polycarbophil 625 mg

Fiber Therapy
for Regularity

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ACTUAL SIZE

90 Tablets

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Distributed by: MAJOR PHARMACEUTICALS
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Lot # & Exp. Date: M-29 / 404-11-10 Hex 11/76

FIBER TABS

calcium polycarbophil tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-2500
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARAMEL (UNII: T9D99G2B1R)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
TALC (UNII: 7SEV7J4RIU)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	white (Off white)		Score	2 pieces
Shape	OVAL		Size	19 mm
Flavor			Imprint Code	CPC;339
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-2500-91	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2010	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part334	09/01/2010	

Labeler - Major Pharmaceuticals (191427277)