### FIBER LAXATIVE - calcium polycarbophil tablet Topco Associates, LLC

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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#### **Topcare Fiber Laxative**

#### **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 or water (8oz.) or other fluid. Taking this product without enough liquid may cause chocking. 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 y	rears	ask a doctor	

#### OTHER INFORMATION

- each caplet contains: calcium 135 mg
- 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.

#### PRINCIPAL DISPLAY PANEL

NDC 36800-465-27 Topcare`

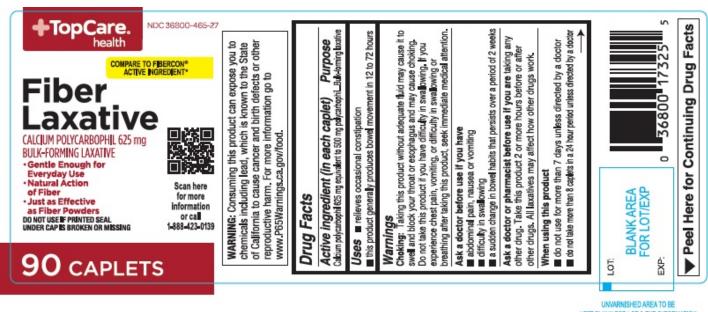
#### COMPARE TO FIBERCON ACTIVE INGREDIENT Fiber Laxative

#### CALCIUM POLYCARBOPHIL 625 mg

#### **BULK-FORMING LAXATIVE**

- Gentle Enough for Everyday Use
- Just as Effective as Fiber Powders

#### DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING 90 CAPLETS



LEFT BLANK FOR LOT & EXP. INFORMATION (LINE DOES NOT PRINT)

## **GLUE AREA** (NO COPY)

# Stop Peeling Here

REV 0321

This product is not manufactured or distributed by Pfizer Consumer lealthcare, the distributor of Fibercons



opcare@topco.com www.topcarebrand.com

Your lotal satisfaction is guaranteed This TopCare® product is laboratory GF) ) GLUTEN

NSTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007 ⊅TOPCO GUAA0321 QUESTIONS? 1-888-423-0139

polyethylene glycol, sodium lauryl sulfate.

colloidal silicon dioxide, crospovidone, hydroxypropyl

Inactive ingredients

calcium carbonate, caramel

Other Information ■ each caplet contains: calcium 135 mg ■ store at room temperature ■ protect contents from

adults & children 12 years & over

2 caplets, 1 to 4 times a day

ask a doctor

children under 12 years

methylcellulose, magnesium stearate,

microcrystaline cellulose

Stop use and ask a doctor if Drug Facts (continued) difficulty in breathing or swallowing you experience chest pain, abdominal

full glass of water (8oz.) or other fluid. Taking this product is normally required to provide full benefit use or severity of constipation dosage will vary according to diet, exercise, previous laxative without enough liquid may cause choking. See choking warning take this product (child or adult dose) with a continued use for 1 to 3 days

medical help or contact a Poison Control Center immediately Ceep out of the reach of children. In case of overdose, get you fail to have a bowel movement after use or have rectal bleeding. These could be signs of a serious condition.

pain, nausea, vomiting

#### FIBER LAXATIVE

calcium polycarbophil tablet

## Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-465 Route of Administration ORAL

l	Active Ingredient/Active Moiety				
l	Ingredient Name	<b>Basis of Strength</b>	Strength		
	CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49) (POLYCARBOPHIL - UNII: W25LM17A4W)	CALCIUM POLYCARBOPHIL	625 mg		

Inactive Ingredients				
Ingredient Name	Strength			
CALCIUM CARBONATE (UNII: H0G9379FGK)				
CARAMEL (UNII: T9D99G2B1R)				
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)				
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				

Product Characteristics				
Color	WHITE (Off white)	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	G147	
Contains				

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:36800-465- 27	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	08/01/2020	

#### Labeler - Topco Associates, LLC (006935977)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Guardian Drug Company		119210276	MANUFACTURE(36800-465)		

Revised: 11/2022 Topco Associates, LLC