

FIBER- calcium polycarbophil tablet, film coated
Western Family Foods Inc

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.

Western Family Fiber Laxative Drug Facts

Active ingredient (in each caplet)

Calcium polycarbophil 625 mg equivalent to 500 mg polycarbophil

Purpose

Bulk-forming laxative

Uses

- relieves occasional constipation to help restore and maintain regularity
- 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
- 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. (1-800-222-1222)

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 product 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.

age	recommended dose	daily maximum
adults and children 12 years of age and over	2 caplets once a day	up to 4 times a day
children under 12 years	consult a physician	

Other information

- each caplet contains: calcium 140 mg and magnesium 10 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

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

Principal Display Panel

CALCIUM POLYCARBOPHIL 625 mg

Bulk-Forming Laxative

FIBER LAXATIVE


FIBER THERAPY FOR REGULARITY

GENTLE ENOUGH FOR EVERYDAY USE

JUST AS EFFECTIVE AS FIBER POWDERS

COMPARE TO FIBERCON® active ingredient

Gluten Free



CALCIUM POLYCARBOPHIL 625 mg
Bulk-Forming Laxative
FIBER LAXATIVE
FIBER THERAPY FOR REGULARITY
GENTLE ENOUGH FOR EVERYDAY USE
JUST AS EFFECTIVE AS FIBER POWDERS

COMPARE TO FIBERCON®
active ingredient*

90 Caplets Gluten Free


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

Drug Facts	<p>Active Ingredient (in each caplet) Calcium polycarbophil 625 mg equivalent to 500 mg polycarbophil.</p> <p>Uses ■ relieves occasional constipation to help restore and maintain regularity ■ this product generally produces 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.</p> <p>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. (1-800-222-1222)</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 product 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%; border-collapse: collapse;"> <tr> <td style="width: 15%;">age</td> <td style="width: 15%;">recommended dose</td> <td style="width: 15%;">daily maximum</td> </tr> <tr> <td>adults and children 12 years of age and over</td> <td>2 caplets once a day</td> <td>up to 4 times a day</td> </tr> <tr> <td>children under 12 years</td> <td colspan="2">consult a physician</td> </tr> </table> <p>Other information ■ each caplet contains: calcium 140 mg and magnesium 10 mg ■ store at 20-25°C (68-77°F)</p> <p>Inactive ingredients caramel, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium lauryl sulfate</p>	age	recommended dose	daily maximum	adults and children 12 years of age and over	2 caplets once a day	up to 4 times a day	children under 12 years	consult a physician	
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47775 3W F4

FIBER

calcium polycarbophil tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55312-477
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)	
CROSPVIDONE (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	BROWN (light)	Score	2 pieces
Shape	CAPSULE (caplet)	Size	19mm
Flavor		Imprint Code	L477
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55312-477-75	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/19/1998	

Labeler - Western Family Foods Inc (192166072)

Revised: 9/2012

Western Family Foods Inc