

FIBER LAXATIVE- calcium polycarbophil tablet, film coated
Kroger Company

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.

Kroger Co. 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

Questions or comments?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredient of FIBERCON®

See back panel

Fiber Laxative

Calcium Polycarbophil 625 mg

BULK-FORMING LAXATIVE

Fiber Therapy for Regularity

As Effective as Fiber Powders

140 CAPLETS

actual size

COMPARE TO the active ingredient of **FIBERCON®**
*See back panel

NDC 30142-477-92



Fiber Laxative

Calcium Polycarbophil 625 mg

BULK-FORMING LAXATIVE

- Fiber Therapy for Regularity
- As Effective as Fiber Powders



actual size

140
CAPLETS

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

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| <p>Drug Facts</p> <p>Active ingredient (in each caplet) Calcium polycarbophil 625 mg equivalent to 500 mg polycarbophil.....Bulk-forming laxative</p> <p>Uses</p> <ul style="list-style-type: none"> relieves occasional constipation to help restore and maintain regularity this product generally produces bowel movement in 12 to 72 hours <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> abdominal pain, nausea, or vomiting a sudden change in bowel habits that persists over a period of 2 weeks <p>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</p> <ul style="list-style-type: none"> 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 <p>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.</p> <p>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</p> <ul style="list-style-type: none"> 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. <table border="1"> <tr> <td>age</td> <td>recommended dose</td> <td>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</p> <ul style="list-style-type: none"> each caplet contains: calcium 140 mg and magnesium 10 mg store at 20-25°C (68-77°F) <p>Inactive ingredients caramel, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium lauryl sulfate</p> <p>Questions or comments? 1-800-632-6900</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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| <p>DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. QUALITY GUARANTEE www.kroger.com</p> <p>*FiberCon® is a registered trademark of Wyeth Holdings Corporation, Madison, NJ 07940. Wyeth Holdings Corporation is not affiliated with The Kroger Co. or this product.</p> <p>GLUTEN FREE</p> | | | | | | | | | | |



: 47792 45 F6

FIBER LAXATIVE

calcium polycarbophil tablet, film coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30 142-477 |
| 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:30 142-477-75 | 1 in 1 CARTON | | |
| 1 | | 90 in 1 BOTTLE | | |
| 2 | NDC:30 142-477-92 | 1 in 1 CARTON | | |
| 2 | | 140 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph not final | part334 | 02/07/1997 | |

Labeler - Kroger Company (006999528)

Revised: 10/2014

Kroger Company