

**FIBER LAXATIVE- calcium polycarbophil tablet, film coated**  
**Geri-Care Pharmaceutical Corp**

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**gc 449(459)**

**Active ingredient (in each caplet)**

Calcium Polycarbophil 625 mg  
(equivalent to 500 mg polycarbophil)

**Purpose**

Bulk-forming laxative

**Uses**

- relieves occasional constipation
- promotes regularity
- this product generally produces a 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.

## 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 laxative 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.

|   |  |
|---|--|
| adults and children 12 years of age and older | Starting dose: 2 caplets once a day<br>Maximum dose: 2 caplets four times a day or as directed by a doctor |
| children under 12 years of age                | consult a doctor   |

## Other information

- **each caplet contains:** calcium 140 mg
- store at controlled room temperature, 68°F-77°F (20°C-25°C)
- protect contents from moisture

**Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

## Inactive ingredients

caramel, cellulose, crospovidone, hypromellose, magnesium silicate, magnesium stearate, mineral oil, PEG, silica, sodium lauryl sulfate, stearic acid

## Package Label

|   |   |   |   |  |                                |                  |
|---|---|---|---|--|--------------------------------|------------------|
| <p><b>Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b> <span style="float: right;"><b>Purpose</b></span><br/>Calcium Polycarbophil 625 mg<br/>(equivalent to 500 mg polycarbophil).....Bulk-forming laxative</p> <p><b>Uses</b> • relieves occasional constipation • promotes regularity<br/>• this product generally produces a bowel movement in 12 to 72 hours</p> <p><b>Warnings</b><br/><b>Choking:</b> 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.<br/><b>Ask a doctor before use if you have</b> • abdominal pain, nausea, or vomiting<br/>• a sudden change in bowel habits that persists over a period of 2 weeks<br/><b>Ask a doctor or pharmacist before use if you are</b> taking any other drug. Take this product 2 or more hours before or after other drugs. All laxatives may affect how other drugs work.<br/><b>When using this product</b> • do not use for more than 7 days unless directed by a doctor<br/>• do not take more than 8 caplets in a 24 hour period unless directed by a doctor<br/><b>Stop use and ask a doctor if</b> 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.<br/><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> | <p>NDC 57896-459-09</p> <p><b>GERI CARE®</b></p> <p><b>FIBER LAXATIVE</b></p> <p><b>CALCIUM POLYCARBOPHIL</b></p> <p>• Relieves Constipation<br/>• Promotes Regularity</p>  <p>Compare to active ingredient in <b>FIBERCON®*</b></p> <p><b>90 Caplets    625 mg each</b></p> | <p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> • 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 laxative 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"> <tr> <td>adults and children 12 years of age and older</td> <td>Starting dose: 2 caplets once a day<br/>Maximum dose: 2 caplets four times a day or as directed by a doctor</td> </tr> <tr> <td>children under 12 years of age</td> <td>consult a doctor</td> </tr> </table> <p><b>Other information</b> • each caplet contains: calcium 140 mg<br/>• store at controlled room temperature, 68°F-77°F (20°C-25°C)<br/>• protect contents from moisture<br/><b>Tamper Evident:</b> Do not use if imprinted seal under cap is missing or broken.</p> <p><b>Inactive ingredients:</b> caramel, cellulose, crospovidone, hypromellose, magnesium silicate, magnesium stearate, mineral oil, PEG, silica, sodium lauryl sulfate, stearic acid.</p> <p><small>*This product is not manufactured or distributed by the owner of the registered trademark FIBERCON®.</small></p> <p>Dist. by: Geri-Care Pharmaceuticals Corp., 1295 Towbin Ave, Lakewood, NJ 08701<br/>1-800-540-3765<br/>REV 0123C</p> | adults and children 12 years of age and older | Starting dose: 2 caplets once a day<br>Maximum dose: 2 caplets four times a day or as directed by a doctor | children under 12 years of age | consult a doctor |
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calcium polycarbophil tablet, film coated

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:57896-459 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

| <b>Ingredient Name</b>                                | <b>Strength</b> |
|---|-----------------|
| <b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)           |                 |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                |                 |
| <b>CROSPVIDONE</b> (UNII: 2S7830E561)                 |                 |
| <b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)          |                 |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)          |                 |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)               |                 |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U) |                 |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)     |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)             |                 |
| <b>CARAMEL</b> (UNII: T9D99G2B1R)                     |                 |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)       |                 |

## Product Characteristics

|                 |                            |                     |          |
|-----------------|----------------------------|---------------------|----------|
| <b>Color</b>    | white (Off white to cream) | <b>Score</b>        | 2 pieces |
| <b>Shape</b>    | OVAL (Caplet)              | <b>Size</b>         | 19mm     |
| <b>Flavor</b>   |                            | <b>Imprint Code</b> | CPC;339  |
| <b>Contains</b> |                            |                     |          |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:57896-459-09 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2015                  |                           |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug        | M007  | 01/01/2004                  |                           |

**Labeler** - Geri-Care Pharmaceutical Corp (611196254)

**Registrant** - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023

Geri-Care Pharmaceutical Corp