CALCIUM POLYCARBOPHIL- calcium polycarbophil tablet CITRAGEN PHARMACEUTICALS, INC.

Fiber Laxative Plus Calcium (Calcium Polycarbophil 625 mg) Tablets

Drug Facts

Active Ingredient (in each caplet)

Calcium Polycarbophil 625 mg (equivalent to polycarbophil 500 mg)

Purpose

Bulk-forming Laxative

Uses

- relieves occasional constipation (irregularity)
- 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 two or more hours before or after other drugs.
- Laxatives may affect how other drugs work.

When using this product

• do not use for more than 7 days unless directed by a doctor

Stop use and ask a 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 overdose, get medical help or contact a Poison Control Center right away

Directions

- take this product (child or adult dose) with a full glass of water (8oz.) or other fluid. Taking this product without enough liquid may cause choking. See choking warning
- adults and children over 12 years of age and over: take 2 caplets, 1 to 4 times per day. Do not take more than 8 caplets in one 24-hour period unless directed by a doctor.
- children under 12 years of age: ask a doctor

Other information

- each caplet contains: calcium 140 mg; sodium 14 mg
- store in a dry place at 15° 30°C (59° 86°F)
- protect contents from moisture

Inactive Ingredients

Croscarmellose Sodium NF, Hydrogenated Vegetable Oil NF, Microcrystalline Cellulose NF and Sodium Chloride USP

Questions or comments?

Phone: +1-510-249-9066, 9AM-5PM PST, Mon-Fri; e-mail: info@citragenpharma.com

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Manufactured by:

CitraGen Pharmaceuticals, Inc., Fremont, CA 94538.

www.citragenpharma.com

Rev. 04/25 R-00

CitraGen Pharmaceuticals, Inc.

NDC: 70369-006-08

Calcium Polycarbophil Tablets 625 mg

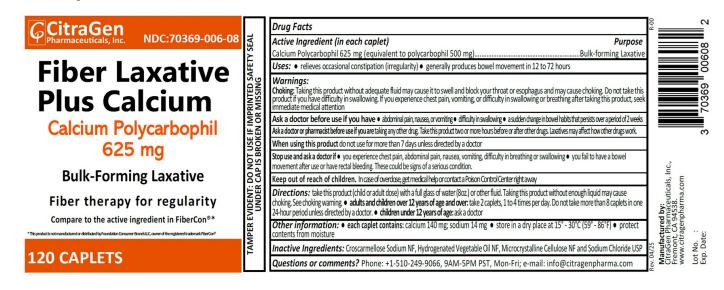
Fiber Laxative Plus Calcium

Calcium Polycarbophil 625 mg

Bulk-Forming Laxative

Fiber Therapy for regularity

120 Caplets



1 This product is not manufactured or distributed by Foundation Consumer Brands LLC, owner of the registered trademark FiberCon®

CitraGen Pharmaceuticals, Inc.

NDC: 70369-006-10

Calcium Polycarbophil Tablets 625 mg Fiber Laxative Plus Calcium Calcium Polycarbophil 625 mg

Bulk-Forming Laxative

Fiber Therapy for regularity

Compare to the active ingredient in FiberCon ®2

240 Caplets



Fiber Laxative Plus Calcium

Calcium Polycarbophil 625 mg

Bulk-Forming Laxative Fiber therapy for regularity

Compare to the active ingredient in FiberCon®*

240 CAPLETS

IMPRINTED I OR MISSING DO NOT USE IF I CAP IS BROKEN SE/ SAFETY

Active Ingredient (in each caplet)

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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 two or more hours before or after other drugs. Laxatives may affect how other drugs work

When using this product do not use for more than 7 days unless directed by a doctor

Stop use and ask a 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 overdose, get medical help or contact a Poison Control Center right away **Directions:** take this product (child or adult dose) with a full glass of water (8oz.) or other fluid. Taking this product without enough liquid may cause choking. See choking warning. • adults and children over 12 years of age and over: tal 2 caplets, 1 to 4 times per day. Do not take more than 8 caplets in one 24-hour period unless directed by a doctor. children under 12 years of age: ask a doctor

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Inactive Ingredients: Croscarmellose Sodium NF, Hydrogenated Vegetable Oil NF, Microcrystalline Cellulose NF and Sodium Chloride USP

Questions or comments?

Phone: +1-510-249-9066, 9AM-5PM PST, Mon-Fri; e-mail: info@citragenpharma.com

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Purpose

Manufactured by: CitraGen Pharmaceuticals, In Fremont, CA 94538. www.citragenpharma.com

2 This product is not manufactured or distributed by Foundation Consumer Brands LLC, owner of the registered trademark FiberCon®

CALCIUM POLYCARBOPHIL

calcium polycarbophil tablet

Product Information

HUMAN OTC DRUG Product Type Item Code (Source) NDC:70369-006

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49) (POLYCARBOPHIL -UNII:W25LM17A4W)

CALCIUM 625 mg **POLYCARBOPHIL**

Inactive Ingredients

Ingredient Name Strength CROSCARMELLOSE SODIUM (UNII: M280L1HH48)

HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

SODIUM CHLORIDE (UNII: 451W47IQ8X)

Product Characteristics

Color white Score no score **CAPSULE** Shape 18mm Size Flavor CG006 **Imprint Code Contains**

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:70369-006- 08	120 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2025					
2	NDC:70369-006- 10	240 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2025					

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC Monograph Drug	M007	07/01/2025						

Labeler - CITRAGEN PHARMACEUTICALS, INC. (024949457)

Registrant - CITRAGEN PHARMACEUTICALS, INC. (024949457)

Establishment								
Name	Address	•	Business Operations					
CITRAGEN PHARMACEUTICALS, INC.		024949457	manufacture(70369-006), analysis(70369-006), pack(70369-006), label(70369-006)					

Revised: 4/2025 CITRAGEN PHARMACEUTICALS, INC.