

FIBER CAPLETS- calcium polycarbophil tablet Bryant Ranch Prepack

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.

Fiber Laxative

Active ingredient (in each caplet)

Calcium polycarbophil 625 mg equivalent to 500 mg polycarbophil

Purpose

Bulk-forming laxative

uses

- 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 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 the reach of children

In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- take this product (child or adult dose) with a full glass of water (8 oz.) or other fluid. Taking this product without enough liquid may cause choking. See choking warning.
- dosage will vary according to diet, exercise, previous laxative use or severity of constipation.
- continued use for 1 or 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 years | ask a doctor |

Other information

- **each caplet contains:** calcium 135mg
- 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

HOW SUPPLIED

NDC: 71335-1075-1: 30 Tablets in a BOTTLE

NDC: 71335-1075-2: 60 Tablets in a BOTTLE

NDC: 71335-1075-3: 120 Tablets in a BOTTLE

Calcium Polycarbophil 625mg Tablet

Packaged by Bryant Ranch Prepack

Burbank, CA 91504

Calcium Polycarbophil 625mg Tablet

LOT 1523487

white capsule G147

Keep tightly closed

Compare To

Fibercon 625mg Tablet

Sunmark

Store at room temp of
20°-25°C (68°-77°F)

30

EXP MM/YY

NDC

7133510751



04436301523487

FIBER CAPLETS

calcium polycarbophil tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71335-1075(NDC:49348-190) |
| 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 |
|--|----------|
| CALCIUM CARBONATE (UNII: H0G9379FGK) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSPVIDONE (UNII: 2S7830E561) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |

| | |
|--|--|
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| CARAMEL (UNII: T9D99G2B1R) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | white | Score | no score |
| Shape | capsule | Size | 19mm |
| Flavor | | Imprint Code | G147 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71335-1075-1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2022 | |
| 2 | NDC:71335-1075-2 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2022 | |
| 3 | NDC:71335-1075-3 | 120 in 1 BOTTLE; Type 0: Not a Combination Product | 02/14/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 09/18/2019 | |

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|--|
| Bryant Ranch Prepack | | 171714327 | REPACK(71335-1075) , RELABEL(71335-1075) |

Revised: 2/2022

Bryant Ranch Prepack