

FIBER LAXATIVE CAPLETS- calcium polycarbophil tablet
Gendose Pharmaceuticals, LLC

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.

GENDOSE - FIBER LAXATIVE CAPLETS (77333-120)

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 PERSIST 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 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 LAXATIVES. 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 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

ADULTS AND CHILDREN OVER 12 YEARS: 2 CAPLETS ONCE A DAY; UP TO 4 TIMES A DAY.

CHILDREN UNDER 12 YEARS: ASK A DOCTOR

OTHER INFORMATION

- EACH CAPLET CONTAINS: CALCIUM 125MG
- STORE AT ROOM TEMPERATURE
- PROTECT CONTENTS FROM MOISTURE

INACTIVE INGREDIENTS

CALCIUM CARBONATE, CARMEL COLOR, CROSPVIDONE, HYPROMELLOSE, MAGNESIUM STEARATE, MALTODEXTRIN, MICROCRYSTALLINE CELLULOSE, POLYETHYLENE GLYCOL, SILICON DIOXIDE, SODIUM LAURYL SULFATE

NDC 77333-120-50

*Compares to the active ingredient in FiberCon®

Fiber Laxative Caplets

Calcium Polycarbophil 625mg

- Gentle Relief of Constipation
- Won't cause gas or bloating
- Effective as fiber powders

UD 50 Caplets (5x10)



(01) 0 03 77333 120 50 8



NDC 77333-120-50

*Compares to the active ingredient in FiberCon®

Fiber Laxative Caplets

Calcium Polycarbophil 625mg

UD 50 Caplets (5x10)

Drug Facts

Active ingredient (in each caplet)	Purpose
Calcium polycarbophil 625 mg (Equivalent to 500 mg polycarbophil)	Bulking 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. 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 accidental 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 fluid 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

Adults and children over 12 years: 2 caplets once a day; up to 4 times a day.
Children under 12 years: ask a doctor

Other information • each caplet contains: calcium 125mg
 • store at room temperature • protect contents from moisture

Inactive ingredients calcium carbonate, caramel color, croscapellone, hypromellose, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium lauryl sulfate.

*This product is not manufactured or distributed by Pfizer, Inc., owner of the registered trademark FiberCon® Caplets. LB12050X09R1

FIBER LAXATIVE CAPLETS

calcium polycarbophil tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-120
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	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CALCIUM CARBONATE (UNII: H0G9379FGK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CROSPOVIDONE (UNII: 2S7830E561)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
CAMEL (UNII: T9D99G2B1R)				
Product Characteristics				
Color	brown (mottled light-brown color with dark specs)	Score	no score	
Shape	OVAL (CAPLET)	Size	19mm	
Flavor		Imprint Code	RP120	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-120-50	50 in 1 BOX	09/02/2022	
1	NDC:77333-120-25	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334		09/02/2022	

Labeler - Gendose Pharmaceuticals, LLC (080257510)