

FIBER LAX- calcium polycarbophil tablet, film coated
PD-Rx Pharmaceuticals, Inc.

Drug Facts

Active ingredient (in each captab)

Calcium polycarbophil 625 mg

Purpose

Bulk-Forming Laxative

(equivalent to polycarbophil 500 mg)

Uses

- relieves occasional constipation
- 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.

Do not use

longer than one week

Ask a doctor before use if you have

- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that lasts over two weeks

Ask a doctor or pharmacist before use if you are

taking any other drug. Take Fiber-Lax two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after using this product.

These may indicate 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 Fiber-Lax 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.

- do not take more than 4 doses in 24 hours
- **adults & children 12 years and over:** 2 captabs 1 to 4 times a day
- **children under 12 years:** ask a doctor

Other information

- **each captab contains:** calcium 140 mg
- store below 30°C (86°F) • do not refrigerate • protect from humidity

Inactive ingredients

Caramel, crospovidone, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, silica, sodium lauryl sulfate and stearic acid

Questions or comments?

Call 1-800-645-2158

TAMPER EVIDENT: DO NOT USE IF BLISTER SEAL IS BROKEN OR DAMAGED

*Rugby Laboratories, Inc. is not affiliated with the owner of the trademark FiberCon®.

Distributed by: **Rugby Laboratories**

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152


[www. Rugbylaboratories.com](http://www.Rugbylaboratories.com)

16 HOW SUPPLIED

Fiber-Lax Tablets are available as follows:

500 mg: Off White, oval, scored tablet, debossed "CPC 339". Available in bottles of 30 captabs (NDC 55289-949-30)

Fiber-Lax

Drug Facts		Drug Facts (continued)
Active Ingredient (in each captab) Calcium polycarbophil 625mg (equivalent to polycarbophil 500 mg)	Purpose Bulk-Forming Laxative	Directions Take Fiber-Lax 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. • do not take more than 4 doses in 24 hours • adults & children 12 years and over: 2 captabs 1 to 4 times a day • children under 12 years: ask a doctor
USES • relieves occasional constipation • generally produces bowel movement in 12 to 72 hours		Other information • each captab contains: calcium 140mg • store below 30°C (86°F) • do not refrigerate • protect from humidity
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 swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.		Inactive Ingredients caramel, crospovidone, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, silica, sodium lauryl sulfate and stearic acid
Do not use longer than one week		Questions or comments? 1-800-645-2158
Ask a doctor before use if you have • abdominal pain, nausea, or vomiting • noticed a sudden change in bowel habits that lasts over two weeks		 GTIN: 00355289949305 SNO: K20C890005 EXP: 11/2022 LOT: K20C89
Ask a doctor or pharmacist before use if you are taking any other drug. Take Fiber-Lax two or more hours before or after other drugs. Laxatives may affect how other drugs work.		
Stop use and ask a doctor if • you have rectal bleeding • you fail to have a bowel movement after using this product. These may indicate a serious condition.		
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.		

NDC 55289-949-30



Fiber-Lax

Bulk-Forming Laxative

- Promotes Regularity
- Non-Habit Forming



3 55289 94930 5

500 mg

Marketed and Packaged By:
PD-Rx Pharmaceuticals, Inc
Oklahoma City, OK 73127
1-405-942-3040 v.8.19.0

30 Captabs
TAMPER EVIDENT: DO NOT USE IF
SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.

FIBER LAX

calcium polycarbophil tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55289-949(NDC:0536-4306)
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, UNSPECIFIED (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (Off-white)	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	CPC;339
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55289-949-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	09/01/2010	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(55289-949)

Revised: 10/2023

PD-Rx Pharmaceuticals, Inc.