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

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Livonia, MI 48152

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



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)			
CROSPOVIDONE, 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: ETJ7Z 6XBU4)	
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				

l	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: 10/2024 PD-Rx Pharmaceuticals, Inc.