FIBER LAX- calcium polycarbophil tablet, film coated Rugby Laboratories

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.

0339-Rugby

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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www. Rugbylaboratories.com

This Package for Households without young children

Rugby

NDC 0536-4306-05

Safe and Effective Relief of Occasional Constipation

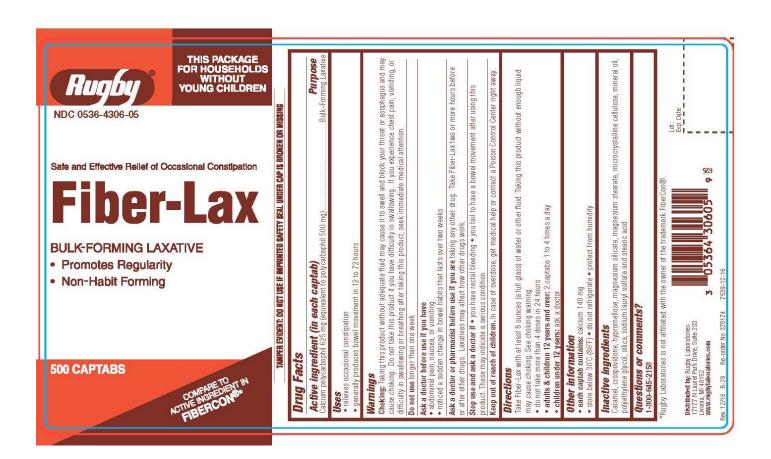
Fiber-Lax

Bulk-Forming Laxative

Promotes Regularity Non-habit Forming

500 Captabs

Comapare to Active ingredient in FIBERCON*



FIBER LAX

calcium polycarbophil tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-4306
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CALCIUM POLYCARBOPHIL (UNII: 8 F0 49 NKY49) (POLYCARBOPHIL - UNII: W25LM17A4W)	CALCIUM POLYCARBOPHIL	625 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CARAMEL (UNII: T9D99G2B1R)		
CROSPO VIDO NE, UNSPECIFIED (UNII: 2S7830E561)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
TALC (UNII: 7SEV7J4R1U)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

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

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-4306- 08	2 in 1 CARTON	09/01/2010	
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-4306-11	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2010	
3	NDC:0536-4306-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/01/2010	

Labeler - Rugby Laboratories (079246066)

Revised: 5/2020 Rugby Laboratories