

FIBER LAX- calcium polycarbophil tablet, film coated
Rugby Laboratories

0339-Rugby

Drug Facts

Active ingredient (in each tablet)

Calcium polycarbophil 625 mg
(equivalent to polycarbophil 500 mg)

Purpose

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Bulk-forming laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

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 Fiber-Lax two 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 tablets in a 24-hour period unless directed by a doctor

Stop use and ask a doctor if

- you fail to have a bowel movement after use or have rectal bleeding.

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 (1-800-222-1222) right away.

Directions

• take this product (child or adult dose) with a full glass of water (8oz.) or other fluid. Taking this product without enough liquid may cause choking. See choking warning

adults and children 12 years and over
children under 12 years

2 tablets, 1 to 4 times per day
ask a doctor

Other information

- **each tablet contains:** calcium 140 mg
- do not use if printed seal under cap is torn or missing
- store in a dry place at 15° - 30°C (59° - 86°F).
- protect contents from moisture

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?

(800) 231-4670

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, owner of the registered trademark FiberCon®

WARNING: This product can expose you to chemicals including lead, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Distributed by: **Rugby Laboratories**

Indianapolis, IN 46268
www.majorpharmaceuticals.com
(800) 616-2471

Rugby

NDC 0536-4306-05

Compare to Active ingredient in FiberCon*

Fiber-Lax


Calcium Polycarbophil 625 mg

Bulk-Forming Laxative

Safe and Effective Relief of Occasional Constipation

Promotes Regularity

500 Tablets



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• abdominal pain, nausea, or vomiting
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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. All laxatives may affect how other drugs work.
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Stop use and ask a doctor if • you fail to have a bowel movement after use or have rectal bleeding. These could be signs of a serious condition.
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Distributed by:
RUGBY® LABORATORIES
Indianapolis, IN 46268
www.majorpharmaceuticals.com
(800) 616-2471

Rev. 07/23 R-25 Re-order No. 370074

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Lot / Exp. Date

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: 8F049NKY49) (POLYCARBOPHIL - UNII: W25LM17A4W)	CALCIUM POLYCARBOPHIL	625 mg

Inactive Ingredients

Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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: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 Drug	M007	09/01/2010	

Labeler - Rugby Laboratories (079246066)

Revised: 12/2023

Rugby Laboratories