

FIBER LAX- calcium polycarbophil tablet, film coated
NCS HealthCare of KY, Inc dba Vanguard Labs

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.

Drug Facts

Active ingredient
(in each captab)

Calcium polycarbophil 625mg

Purpose

Bulk-Forming Laxative

(equivalent to polycarbophil 500mg)

Use(s)

- 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 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

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 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 140mg
- 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 and Comments?

Call 1-800-645-2158, 9am - 5pm ET, Monday - Friday

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®.

Fiber-Lax is distributed by Rugby Laboratories, Inc.

Rugby ®

Duluth, Georgia 30097

www.Rugbylaboratories.com

Principal Display Panel

Fiber-Lax Captabs

VLI NDC 0615-5532-39
**FIBER-LAX
 CAPTABS**

SEE
 WARNINGS
 ON REVERSE

LOT
 5532
 EXP
 05344306539

BULK FORMING
 LAXATIVE
 TAMPER
 EVIDENT

11037-39

QTY
 30

MFG BY CONTRACT
 for RUGBY
 (NDC 0536-4306-05)
 PKG BY VANGARD
 GLASGOW, KY 42141

(Mfg for Rugby, NDC 0536-4306-05)

Fiber-Lax Captabs

Received: _____

24	16	8
31	23	7
30	22	6
29	21	5
28	20	4
27	19	3
26	18	2
25	17	1

START DATE _____ START TIME _____

STORE AT 20°-25°C (68°-77°F)
 (SEE USP CONTROLLED ROOM TEMPERATURE)
 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 in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

Each captab contains calcium polycarbophil 625 mg (equivalent to polycarbophil 500 mg)
 Other Information: Each captab contains calcium 140 mg
 See Package Label Binder for Drug Facts, Dosage Information and Warnings

FOR INSTITUTIONAL USE ONLY

16	8
30	23
29	22
28	21
27	20
26	19
25	18
24	17
17	9
1	1

Pkg By Vanguard, Glasgow, KY 42141 FIBER-LAX CAPTAB LOT 5532 	Pkg By Vanguard, Glasgow, KY 42141 FIBER-LAX CAPTAB LOT 5532 	Pkg By Vanguard, Glasgow, KY 42141 FIBER-LAX CAPTAB LOT 5532 	10326 Rev 00 Vanguard, Inc. Glasgow, KY 42141
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Omnicare 24 The overall configuration of this package is a trademark of Omnicare, Inc. 17 9 1

FIBER LAX

calcium polycarbophil tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:06 15-5532(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
CROSPVIDONE (UNII: 68401960MK)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYPMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARAMEL (UNII: T9D99G2B1R)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	WHITE (Beige)	Score	2 pieces
Shape	CAPSULE ((Oblong bisect))	Size	19mm
Flavor		Imprint Code	CPC;339
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-5532-31	31 in 1 BLISTER PACK		
2	NDC:0615-5532-39	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	09/01/2010	

Labeler - NCS HealthCare of KY, Inc dba Vanguard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, Inc dba Vanguard Labs		050052943	RELABEL(0615-5532) , REPACK(0615-5532)

Revised: 3/2012

NCS HealthCare of KY, Inc dba Vanguard Labs