CALCIUM POLYCARBOPHIL 625 MG- calcium polycarbophil 625 mg tablet Reliable 1 Laboratories LLC

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.

Calcium Polycarbophil 625 mg

Drug Facts

Active ingredient (in each caplet)

Calcium polycarbophil 625 mg (equivalent to polycarbophil 500 mg)

Purpose

Bulk-Forming Laxative

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 cuase 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 this product 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 prodcut

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 right away.

Drug Facts continued on back of label

Directions

- take caplets 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.
- take dose up to 4 times daily
- do not take more than 8 caplets in 24 hours
- adults & children 12 years and over: 2 caplets
- children under 12 years: ask a doctor

Other information

- each caplet contains: calcium 140 mg
- store at 15°-30°C (59°-86°F)
- do not refrigerate
- protect from humidity

Inactive ingredients carob powder, croscarmellose sodium, HPMC, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide

Questions or comments? call 516-341-0666,

8:30 am - 4:30 pm ET, Monday-Friday

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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Distributed by: Reliable 1 Laboratories LLC, Valley Stream, NY 11580

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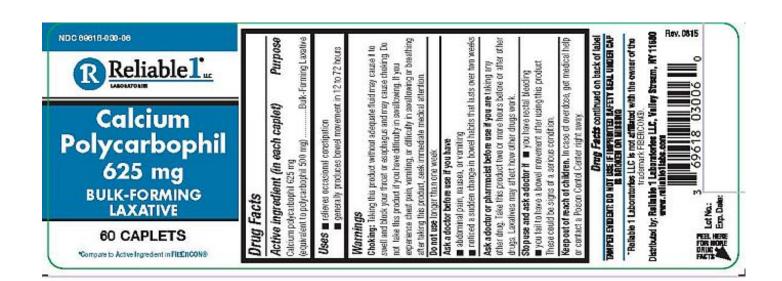
NDC 69618-030-06

Calcium Polycarbophil 625mg

Bulk-Forming Laxative

90 Caplets

*Compare to Active Ingredient in FIBERCON®



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CALCIUM POLYCARBOPHIL 625 MG

calcium polycarbophil 625 mg tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-030	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety				
ı	Ingredient Name	Basis of Strength	Strength		
	CALCIUM POLYCARBOPHIL (UNII: 8F049NKY49) (POLYCARBOPHIL - UNII: W25LM17A4W)	CALCIUM POLYCARBOPHIL	625 mg		

ı	Inactive Ingredients	
	Ingredient Name	Strength

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CAROB (UNII: 5MG5Z946UO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	

Product Characteristics				
Color	white	Score	2 pieces	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	AP;067	
Contains				

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69618- 030-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015			
2	NDC:69618- 030-09	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015			
3	NDC:69618- 030-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2015			



Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	11/01/2015		

Labeler - Reliable 1 Laboratories LLC (079718111)

Revised: 10/2021 Reliable 1 Laboratories LLC