FIBER LAXATIVE - methylcellulose tablet Topco Associates, 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.

Topco Fiber Laxative caplets

ACTIVE INGREDIENT(in each caplet)

Methylcellulose 500 mg

PURPOSE

Bulk-forming laxative

USE(S)

- relieves occasional constipation to help restore and maintain regularity
- generally produces a bowel movement in 12-72 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.

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

WHEN USING THIS PRODUCT

- do not use laxative products for a period longer than one week unless directed by a doctor.
- do not use if you are on a low salt diet unless directed by a doctor.

STOP USE AND ASK DOCTOR IF

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

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

DIRECTIONS

This product generally produces effect in 12-72 hours

- take this product (child or adult) dose with atleast 8 ounces (a full glass) of water or other fluid
- taking this product without enough liquid may cause choking, see choking warning.

AGE	DOSE	MAXIMUM DOSE
adults & children 12 years & over	2 caplets	up to 6 times daily
children 6 to 11 years	1 caplet	up to 6 times daily
children under 6 years	ask a doctor	ask a doctor

OTHER INFORMATION

- each caplet contains: sodium 10 mg
- store below 25°C (77°F)
- protect contents from moisture
- keep tightly closed

INACTIVE INGREDIENTS

citric acid, colloidal silicondioxide, crospovidone, FD&C yellow no.6 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium bicarbonate, sodium chloride, sodium lauryl sulfate.

PRINCIPAL DISPLAY PANEL

Topcare Health

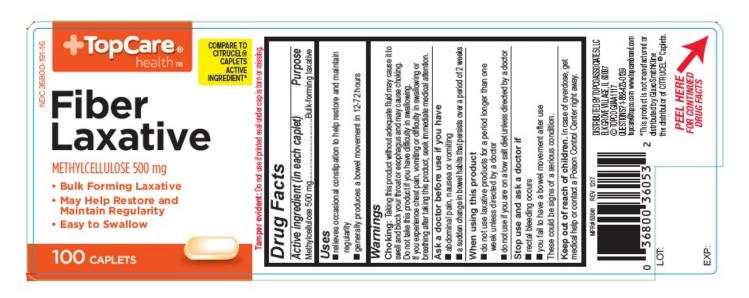
COMPARE TO CITRUCEL® CAPLETS ACTIVE INGREDIENT*

NDC 36800-191-16

Fiber Laxative

METHYLCELLULOSE 500 mg

- Bulk Forming Laxative
- May Help Restore and Maintain Regularity
- Easy to swallow





This Top Care® product is laboratory tested to guarantee its highest quality Your total satisfaction is guaranteed.

Inactive ingredients dincad, coloidal sticon doxida oxpoxidone, FD&C yelow no. 6 aluminum tale, magnesium steatate microorystaline celutose, sodum bicarbonate, sodum chorida, sodum tauyi sudate



Other information ■ each caplet contains: sodium 10 mg ■ store below 25°C (77°F) ■ protect contents from moisture ■ keep fightly closed

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Directions

Drug Facts (continued)

FIBER LAXATIVE

methylcellulose tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-191
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
METHYLCELLULOSE (4000 CPS) (UNII: MRJ667KA5E) (METHYLCELLULOSE (4000 CPS) - UNII:MRJ667KA5E)	METHYLCELLULOSE (4000 CPS)	500 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics			
Color	ORANGE	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	G188
Contains			

l	Packaging			
	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1 NDC:36800-191-	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	12/01/2017	

Labeler - Topco Associates, LLC (006935977)

Establishment			
Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(36800-191)

Revised: 11/2022 Topco Associates, LLC