SUNMARK FIBER LAXATIVE - methylcellulose tablet Strategic Sourcing Services 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.

Sunmark Fiber Caplets

Active ingredient (in each caplet)

Methylcellulose 500 mg

Purpose

Bulk-forming laxative

Uses

- 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 a 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 and 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 silicon dioxide, crospovidone, FD&C yellow 6 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium bicarbonate, sodium chloride, sodium lauryl sulphate

Principal Display Panel

sunmark COMPARE TO CITRUCEL[®] CAPLETS ACTIVE INGREDIENT* fiber laxative Bulk-Forming Laxative Daily source of 100% soluble fiber METHYLCELLULOSE 500 mg THE FIBER WITH NO EXCESS GAS 100 CAPLETS





SUNMARK FIBER LA methylcellulose tablet	XATIVE					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:49348		8-541		
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingredient Name			Basis of St	rength	Strength	
METHYLCELLULOSE (4000 CPS CPS) - UNII:MRJ667KA5E)	5) (UNII: MRJ667KA5E) (METH)	YLCELLULOSE (4000	METHYLCELLUI (4000 CPS)	LOSE	500 mg	
Inactive Ingredients						
Ingredient Name			Str	Strength		
ANHYDROUS CITRIC ACID (UNII	XF417D3PSL)					
SILICON DIOXIDE (UNII: ETJ7Z6X	BU4)					
CROSPOVIDONE (UNII: 257830E	561)					

FD&C YELLOW NO	. 6 (UNII: H77VEI93A8)					
	MAGNESIUM STEARATE (UNII: 70097M6I30)					
	IE CELLULOSE (UNII: OP1R32D61U)					
SODIUM BICARBO	NATE (UNII: 8MDF5V39QO)					
SODIUM CHLORIDE	(UNII: 451W47IQ8X)					
SODIUM LAURYL S	ULFATE (UNII: 368GB5141J)					
Product Chara	cteristics					
Color	orange	Scor	9	no score		
Shape	CAPSULE (Caplet)	Size		19mm		
Flavor		Impri	int Code	G188		
Contains						
Packaging						
# Item Code	Package Description		Marketing Start Date	Marketing End Date		
1 NDC:49348-541- 10	NDC:49348-541- 10 in 1 BOTTLE; Type 0: Not a Combination Product		09/26/2019			
Marketing I	nformation					
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date		
OTC monograph not final	part334		09/26/2019			

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Guardian Drug Company (119210276)

Establishment					
Name	Address	ID/FEI	Business Operations		
Guardian Drug Company		119210276	manufacture(49348-541)		

Revised: 1/2022

Strategic Sourcing Services LLC