SENNA S- docusate sodium, sennosides tablet TOP CARE (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.

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6-12 hours

Warnings

Do not use

- if you are now taking mineral oil, unless directed by a doctor
- laxative products for longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that continues over a period of 2 weeks

Stop use and ask a doctor if

you have rectal bleeding or fail to have a bowel movement after use of a laxative. These may indicate a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

• take preferably at bedtime or as directed by a doctor

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adults and children 12 years of age and over	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

Other information

- **each tablet contains**: calcium 20 mg
- each tablet contains: sodium 6 mg LOW SODIUM
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

carnauba wax*, croscarmellose sodium, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake*, FD&C red #40 aluminum lake*, FD&C yellow #6 aluminum lake, hypromellose*, magnesium stearate, maltodextrin*, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol*, silicon dioxide, sodium benzoate*, stearic acid, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO SENOKOT-S® ACTIVE INGREDIENTS†

Vegetable Laxative

+ Stool Softener

DOCUSATE SODIUM 50 mg • STOOL SOFTENER

SENNOSIDES 8.6 MG • LAXATIVE

TABLETS

GLUTEN FREE

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

†This product is not manufactured or distributed by Purdue Products L.P., distributor of Senokot-S®.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

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www.topcarebrand.com

Product Labeling



TOPCARE HEALTH Vegetable Laxative + Stool Softener

SENNA S					
docusate sodium, sennosides t	ablet				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Sou	Item Code (Source) NDC:36800-08		0-085
Route of Administration	ORAL				
Active Ingredient/Active 1	Moiety				
Ingredient Name		Basis of S	Strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE	DOCUSATE SODIUM		
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)		SENNOSIDES	s	8.6 mg	

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ALUMINUM OXIDE (UNII: LMI2606933)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	TCL081;0805;AV;S35
Contains			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-085- 60	1 in 1 BOX	12/31/2015	
1	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2 NDC:36800-085- 12	1 in 1 BOX	12/31/2015	
2	120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	12/31/2015	

Revised: 10/2019

TOP CARE (Topco Associates LLC)