

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

age	starting dosage	maximum dosage
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.**

TOPCARE HEALTH Vegetable Laxative + Stool Softener

SENNA S

docusate sodium, sennosides tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-085
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM 50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)		SENNOSIDES 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)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

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

Packaging			
#	Item Code	Package Description	Marketing Start Marketing End

#	Item Code	Package Description	Date	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	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

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