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 30 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

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, talc, titanium dioxide

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

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 Avrio Health L.P., distributor

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

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Product Labeling



SENNA S

docusate sodium, sennosides tablet

Product	Inform	ation
Product		ation

Product Type HUMAN OTC DRUG	Item Code (Source)	NDC:36800-783
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Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	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			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
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	PSD22
Contains			

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:36800- 783-60	1 in 1 BOX	07/31/2019			
1		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				
2	NDC:36800- 783-12	1 in 1 BOX	07/31/2019			
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	07/31/2019		

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

Revised: 11/2022 TOP CARE (Topco Associates LLC)