SENNA-S- docusate sodium 50 mg sennosides 8.6 mg tablet, film coated AACE PHARMACEUTICALS, INC.

SPL UNCLASSIFIED SECTION

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.

ACTIVE INGREDIENT (IN EACH TABLET)

Docusate Sodium 50 mg Sennosides 8.6 mg

PURPOSE

Stool softener

Stimulant laxative

USES

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

WARNINGS

Do not use

- this product if you are presently 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
- do not exceed maximum dosage

age	starting dosage	maximum dosage
adults and children 12 years of age or older	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 4 mg, sodium 8 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, stearic acid, titanium dioxide

PRINCIPAL DISPLAY PANEL

Senna-S

Docusate Sodium 50 mg & Sennosides 8.6 mg

NDC 71406-106-01. 71406-106-10

Stool Softner/Laxative

stool softner plus natural vegetable laxative

*Compare to the active ingredients in SENOKOT-S $^{ ext{@}}$

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

Manufactured by:

AACE Pharmaceuticals, Inc. Fairfield, NJ 07004

aacepharma.com

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot-S $^{\circledR}$.







Other information ■ each tablet contains: calcium 4 mg, sodium 8 mg
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose magnesium stearate, microcrystalline cellulose, polyethylene glycol, stearic

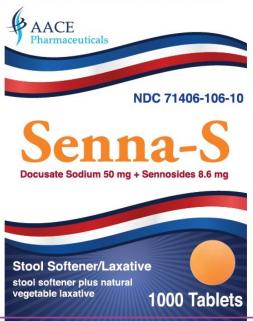
acid, titanium dióxide Manufactured by:

AACE Pharmaceuticals, Inc., Fairfield, NJ 07004 aacepharma.com L-103 Rev. 00 Unvarnished

LOT and EXP AREA







*Compare to active ingredient in Senokot-S®

Drug Facts (continued)

Directions ■ take preferably at bedtime or as directed by a doctor
■ do not exceed maximum dosage

age	starting dosage	maximum dosage
adults and children 12 years of age or older	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 meach tablet contains: calcium 4 mg, sodium 8 mg m store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, D&C Yellow #10 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, titanium dioxide

Distributed by:

AACE Pharmaceuticals, Inc.

Fairfield N 107004

Fairfield, NJ 07004 aacepharma.com

Made in USA Rev. 01

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered tradmark Senokot-S®

Unvarnished LOT and EXP AREA

SENNA-S

docusate sodium 50 mg sennosides 8.6 mg tablet, film coated

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71406-106 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: M280L1HH48)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	9mm	
Flavor		Imprint Code	S6	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71406- 106-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2019	
2	NDC:71406- 106-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	08/30/2019	

Labeler - AACE PHARMACEUTICALS, INC. (080630748)

Revised: 1/2024 AACE PHARMACEUTICALS, INC.