VEGETABLE LAXATIVE AND STOOL SOFTNER- docusate sodium and sennosides tablet, coated 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.

Vegetable Laxative and Stool Softner

Drug Facts

Active ingredients (in each tablet)	Purposes
Docusate sodium 50 mg	Stool softener
Sennosides 8.6 mg	Laxative

Uses

- relieves occasional constipation (irregularity)
- generally, produces bowel movement in 6 to 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
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auuits ariu children 12 years 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	½ tablet once a	1 tablet twice a
under 6 years	day	day
children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains: calcium 20 mg, sodium 3 mg (low sodium)
- store between 20-25°C (68-77°F)

Inactive ingredients

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

Questions?

Call **1-888-423-0139**

PRINCIPAL DISPLAY PANEL - 60 Tablet Bottle Carton

NDC 36800-163-60

*Compare to the active ingredients in Senakot-S®

Senna-S

DOCUSATE SODIUM 50 mg STOOL SOFTENER

SENNOSIDES 8.6 mg LAXATIVE

Vegetable laxative ingredient plus stool softener

60 TABLETS actual size

Senna-S

DOCUSATE SODIUM 50 mg STOOL SOFTENER SENNOSIDES 8.6 mg LAXATIVE

Vegetable laxative ingredient plus stool softener

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Drug Facts (continued)

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

REV.00-122020 CT3680016360

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

KEEP OUTER CARTON FOR COMPLETE PRODUCT INFORMATION

VEGETABLE LAXATIVE AND STOOL SOFTNER

docusate sodium and sennosides tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-938

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
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Anhydrous Dibasic Calcium Phosphate (UNII: L11K75P92J)	
FD&C Yellow No. 6 (UNII: H77VEI93A8)	
Aluminum Oxide (UNII: LMI26O6933)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
T-1- (INIII, 75 F)/7/4 D 1 I I)	

Talc (UNII: 7SEV7J4R1U)

Titanium Dioxide (UNII: 15FIX9V2JP)

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	S153
Contains			

Packaging

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-938- 60	1 in 1 CARTON	05/01/2021	
1		60 in 1 BOTTLE; 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	05/01/2021		

Labeler - TOPCO ASSOCIATES LLC (006935977)

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