

NATURAL VEGETABLE LAXATIVE WITH STOOL SOFTENER- docusate sodium and sennosides tablet

Medline Industries

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.

Natural Vegetable Laxative

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 lasts over 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 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 20 mg**
- each tablet contains: **sodium 6 mg** VERY 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 **1-800-MEDLINE (633-5463) Monday-Friday 9AM-5PM CST**

Principal Display Panel

**Compare to the active ingredients in Senokot-S®

NATURAL VEGETABLE LAXATIVE

WITH STOOL SOFTENER

Gentle, Overnight Relief of Constipation

Docusate Sodium, 50 mg

Sennosides, 8.6 mg

TABLETS

Distributed by: Medline Industries, Inc.

Mundelein, IL 60060 www.medline.com 1-800-Medline

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

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

Product Label

MEDLINE NDC 53329-679-62
 **Compare to the active ingredients in Senokot-S®

NATURAL VEGETABLE LAXATIVE WITH STOOL SOFTENER

Gentle, Overnight Relief of Constipation

Docosate Sodium, 50 mg
 Senosides, 8.6 mg

60 TABLETS

Drug Facts

Active Ingredients (in each tablet)

Docosate sodium 50 mg	Stool softener
Senosides 8.6 mg	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.

Drug Facts (continued under label)
 *This product is not manufactured or distributed by Purdue Products L.P., distributor of Senokot-S®.
 Distributed by: Medline Industries, Inc., Mundelein, IL 60060
 www.medline.com 1-800-Medline

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Drug Facts (continued)

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

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NATURAL VEGETABLE LAXATIVE WITH STOOL SOFTENER

docusate sodium and senosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-679
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M01JX) (SENNOSIDES - UNII:3FYP5M01JX)	SENNOSIDES	8.6 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

CALCIUM PHOSPHATE, DIBASIC, 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 (UNII: 532B59J990)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
STEARIC ACID (UNII: 4ELV7Z65AP)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ALUMINUM OXIDE (UNII: LM26O6933)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-679-62	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/01/2017	

Labeler - Medline Industries (025460908)