

STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium and sennosides tablet

Strategic Sourcing Services 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

Stimulant laxative

Uses

- for overnight relief from occasional constipation (irregularity)
- generally produces bowel movement in 6 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are now taking mineral oil, 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 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 only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses.

adults and children 12 years and older	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2	ask a doctor

Other information

- **each tablet contains:** calcium 30 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, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol*, silicon dioxide, sodium benzoate*, stearic acid, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Colace® 2-IN-1†

Stool Softener

+ Stimulant Laxative

Docusate sodium 50 mg

Sennosides 8.6 mg

For overnight relief of occasional constipation

Tablets

†This product is not manufactured or distributed by Avrio Health L.P., distributor

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0395
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
CARNAUBA WAX (UNII: R12CBM0EIZ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	TCL097;PSD21;S44	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62011-0395-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2018	08/29/2025
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334		12/31/2018	08/29/2025

Labeler - Strategic Sourcing Services LLC (116956644)

