

**STOOL SOFTENER- docusate sodium and sennosides capsule, gelatin coated
CVS**

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.

STOOL SOFTENER

DRUG FACTS

Active ingredients (in each softgel)	Purpose
Docusate sodium 50 mg	Stool softener
Sennosides 8.6 mg	Stimulant Laxative

Uses

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

Warnings

Do not use

- laxative products for longer than 1 week unless told to do so by a doctor
- if you are presently taking mineral oil, unless told to do so 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 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 of age or over	take 2-4 softgels daily
children 6 to under 12 years of age	take 1-2 softgels daily
children 2 to under 6 years of age	take upto 1 softgel daily
children under 2	ask a doctor

Other information

- **each softgel contains:** calcium 2 mg and sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

- Keep tightly closed

Inactive ingredients

Aerosil, beeswax, FD&C Red No.40, gelatin, glycerin, light liquid paraffin, povidone (PVP K-30), purified water, sodium carboxymethylcellulose, sorbitol solution, soya lecithin, titanium dioxide

Questions?

Call **1-888-333-9792** Monday-Friday 9AM-5PM EST

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL

♥CVSHealth™

Compare to the
active ingredients in
COLACE® 2-IN-1*

Liquid Filled Softgels

NDC 69842-319-60

Stool Softener

DOCUSATE SODIUM, 50 mg

SENNOSIDES, 8.6 mg

Plus stimulant laxative

Package Contains One Bottle

60 SOFTGELS

Actual Size

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark COLACE® 2-IN-1.



STOOL SOFTENER			
docusate sodium and sennosides capsule, gelatin coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-319
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: 3FYP5M0IUX) (SENNOSIDES - UNII:3FYP5M0IUX)		SENNOSIDES	8.6 mg
Inactive Ingredients			
Ingredient Name			Strength

SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIO XIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (OPAQUE)	Score	no score
Shape	CAPSULE (SOFTGEL)	Size	12mm
Flavor		Imprint Code	584
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-319-60	1 in 1 CARTON	03/15/2018	
1		60 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	03/15/2018	

Labeler - CVS (062312574)