

STOOL SOFTENER WITH STIMULANT LAXATIVE- docusate sodium and sennosides tablet

P & L Development, 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

- relieves 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 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 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 21 mg
- **each tablet contains:** sodium 5 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 red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium benzoate, stearic acid, talc, titanium dioxide

Questions or comments?

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

Principal Display Panel

stool softener + stimulant laxative

docusate sodium 50 mg

(stool softener)

sennosides 8.6 mg

(stimulant laxative)

tablets

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

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

*This product is not manufactured or distributed by Avrio Health LP., distributor of

Colace® 2-IN-1

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label

wb wellness basics
stool softener + stimulant laxative
 docusate sodium 50 mg (stool softener)
 sennosides 8.6 mg (stimulant laxative)
 100 tablets

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Drug Facts (continued under label)
 *This product is not manufactured or distributed by Avrio Health LP, distributor of Colace® 2-IN-1.

Actual Size

Distributed by: **PL Developments**
 200 Hicks Street, Westbury, NY 11590

3 59726 48410 7
 Lot No.: Exp. Date:
 PLD-D677A LB007897

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Drug Facts (continued)
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WELLNESS BASICS Stool Softener

STOOL SOFTENER WITH STIMULANT LAXATIVE

docusate sodium and sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-878
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
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-878-40	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2020	
2	NDC:59726-878-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/29/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/29/2020	

Labeler - P & L Development, LLC (800014821)

