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

- for overnight relief from occasional constipation (irregularity)
- generally produces bowel movement in 6 to12 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 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 30 mg
- **each tablet contains:** sodium 6 mg VERY LOW SODIUM
- store at 25ºC (77ºF); excursions permitted between 15-30ºC(59-86ºF)

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*, silcon 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

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

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:59726-829
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: 3WQ0SDW1A)	
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:59726-829-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2018	12/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/31/2018	12/31/2025

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023 P & L Development, LLC