STOOL SOFTENER WITH STIMULANT LAXATIVE- docusate sodium, sennosides tablet Family Dollar (FAMILY WELLNESS)

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	take 2-4
years and older	tablets daily
children 6 to under 12	take 1-2
years of age	tablets daily
children 2 to under 6	take up to 1
years of age	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 pjosphate 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

Questions or comments?

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

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS OF COLACE® 2-IN-1†

Stool Softener

With Stimulant Laxative

Docusate sodium 50 mg

Sennosides 8.6 mg

Relieves Constipation

^{*}contains one or more of these ingredients

TABLETS

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 L.P., distributor of Colace® 2-IN-1.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Product Label



FAMILY WELLNESS Stool Softener

STOOL SOFTENER WITH STIMULANT LAXATIVE

docusate sodium, sennosides tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-829
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: M280L1HH48)		
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		

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:55319- 829-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2019	10/25/2024

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not	nort224	02/21/2010	10/25/2024	

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Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 10/2021 Family Dollar (FAMILY WELLNESS)