

STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium and sennosides tablet
Safeway, Inc.

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 told to do so 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 20 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 **1-888-723-3929** Monday-Friday 7AM-6PM PST

Principal Display Panel

COMPARE TO Colace® 2-IN-1 active ingredients†

Stool Softener

Plus Stimulant Laxative

DOCUSATE SODIUM 50 mg

SENNOSIDES 8.6 mg

For overnight relief of occasional constipation

- Gentle
- Dependable

Relief in 6-12 hours

TABLETS

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

Colace® 2-IN-1.

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

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Product Label

Signature Care
Quality Guaranteed

Stool Softener Plus Stimulant Laxative
DOCUSATE SODIUM 50 mg
SENNOSIDES 8.6 mg

For overnight relief of occasional constipation
• Gentle
• Dependable
Relief in 6-12 hours

Actual Size
200 TABLETS

Compare to Colace® 2-IN-1 active ingredients! NDC 21130-829-20

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

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

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Docusate sodium 50 mg
Sennosides 8.6 mg

Purpose
Stool softener
Stimulant laxative

Uses
■ for overnight relief from occasional constipation (irregularity)
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Ask a doctor before use if you have
■ stomach pain ■ nausea ■ vomiting
■ 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 feel you have a bowel movement after use of a laxative. These may indicate a serious condition.

Other information
■ each tablet contains calcium 30 mg
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*contains one or more of these ingredients

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Drug Facts (continued)

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PEEL HERE

SIGNATURE CARE Stool Softener Plus Stimulant Laxative

STOOL SOFTENER PLUS STIMULANT LAXATIVE			
docusate sodium and sennosides tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-829
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)	
CROSCARMELOSE 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:21130-829-20	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2018	

Marketing Information

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

Labeler - Safeway, Inc. (009137209)