

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 presently 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 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, titanium dioxide

Questions or comments?

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

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
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Compare to Colace® 2-IN-1 active ingredients*
NDC 21130-878-20

Stool Softener Plus Stimulant Laxative

DOCUSATE SODIUM 50 mg
SENNOSIDES 8.6 mg

For overnight relief of occasional constipation

- Gentle
- Dependable

Actual Size

200 TABLETS

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Drug Facts (continued under label)

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SIGNATURE CARE Stool Softener

STOOL SOFTENER PLUS STIMULANT LAXATIVE

docusate sodium and sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-878
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: 3FYP5M0JJX) (SENNOSIDES - UNII:3FYP5M0JJX)		SENNOSIDES	8.6 mg

Inactive Ingredients		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)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
ALUMINUM OXIDE (UNII: LMI26O6933)		

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:21130-878-20	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/30/2020	

Labeler - Safeway, Inc. (009137209)