STOOL SOFTENER STIMULANT LAXATIVE- docusate sodium and sennosides tablet QUALITY CHOICE (Chain Drug Marketing Association)

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 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
childrens 6 to under 12 years of age	take1-2 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 25°C(77°F), excursion 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*, sillicon dioxide, sodium benzoate*, stearic acid, talc*, titanium dioxide

Questions or comments?

Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

Principal Display Panel

**Compare to the Active Ingredients in Colace® 2-IN-1

STOOL SOFTENER

Plus Stimulant Laxative

Docusate sodium, 50 mg

Sennosides, 8.6 mg

Effective

Reliable

Comfortable

TABLETS

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

^{*}contains one or more of these ingredients

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

Distributed by C.D.M.A. Inc.© 43157 W. 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com

Product Label



QUALITY CHOICE Stool Softener Plus Stimulant Laxative

STOOL SOFTENER STIMULANT LAXATIVE			
docusate sodium and sennosides tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-875
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)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
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 RED NO. 40 (UNII: WZB9127XOA)	

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
	NDC:63868- 875-01	100 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 Drug	M007	12/31/2018	