

STOOL SOFTENER PLUS STIMULANT LAXATIVE- docusate sodium and sennosides tablet

TOP CARE (Topco Associates 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 to 12 hours

Warnings

Do not use

- laxative products for longer than 1 week unless directed 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 could be signs of 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, maltodextrin*, microcrystalline cellulose, polyethylene glycol*, polyvinyl alcohol*, silicon dioxide, sodium benzoate*, stearic acid, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call toll free **1-888-423-0139**

Principal Display Panel

COMPARE TO COLACE® 2-IN-1 ACTIVE INGREDIENT†

Stool Softener

Plus Stimulant Laxative

DOCUSATE SODIUM 50 mg STOOL SOFTENER

SENNOSIDES 8.6 mg STIMULANT LAXATIVE

For Overnight Relief Of Occasional Constipation

- Effective
- Reliable
- Comfortable

TABLETS

GLUTEN FREE

†This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® 2-IN-1

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.comwww.topcarebrand.com

Product Label

NDC 36800-084-01



Stool Softener + Stimulant Laxative

DOCUSATE SODIUM 50 mg
STOOL SOFTENER
SENNOSIDES 8.6 mg
STIMULANT LAXATIVE

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



For Overnight Relief Of Occasional Constipation:

- Effective
- Reliable
- Comfortable

actual size

100 TABLETS

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007 © TOPCO
PLVA0618 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
Visit here for more information:
<http://topbrnds.com/48zr8q>
PLD-H9T
FC004542



✓ QUALITY GUARANTEED



Lot No.:

Exp. Date:

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TOPCARE HEALTH Stool Softener + Stimulant Laxative

STOOL SOFTENER PLUS STIMULANT LAXATIVE

docusate sodium and sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-084
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
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)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL097;0806;AV;S44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-084-01	1 in 1 BOX	01/31/2016	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	01/31/2016	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

