

STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled **Strategic Sourcing Services 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 ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless told to do so 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 could be signs of a serious condition.
- you need to use a laxative for more than 1 week

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 or in divided doses.

adults and children 12 years and over	take 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

Other information

- **each softgel contains:**sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

D&C red #33*, edible ink, FD&C blue #1*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitan, sorbitol, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

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

Principal Display Panel

COMPARE TO COLACE® REGULAR STRENGTH STOOL SOFTENER ACTIVE INGREDIENT†

stool softener

Relief of occasional constipation

Docusate Sodium 100 mg

Stool Softener Laxative

SOFTGELS

†This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular Strength Stool Softener.

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

Another Quality Product Distributed By Mckesson

One Post Street, San Francisco, CA 94104

www.sunmarkbrand.com

Product Label



sunmark[®]
COMPARE TO COLACE[®]
REGULAR STRENGTH
STOOL SOFTENER
ACTIVE INGREDIENT[†]
NDC 70677-0034-1

stool softener

Relief of occasional constipation
Docusate Sodium 100 mg
Stool Softener Laxative

100 SOFTGELS

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Drug Facts (continued under label)

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PLD-C2L
L9005040

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Lot No.: _____ Exp. Date: _____

PEEL HERE

Drug Facts (continued)

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SUNMARK Stool Softener Laxative

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-0034
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red, white	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10;SCU2;D1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0034-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2017	
2	NDC:70677-0034-2	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/31/2017	

Labeler - Strategic Sourcing Services LLC (116956644)