

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

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

- for relief of occasional constipation and irregularity
- this product generally produces bowel movement in 12 to 72 hours

Warnings

Do not use

if you are presently taking mineral oil, unless directed by a doctor.

Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- a sudden change in bowel habits that lasts more than 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement after using 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 with a glass of water

adults and children 12 years and over	take 1 to 3 softgels daily. This dose may be taken as a single daily dose or in divided doses.
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 5 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol

Questions or comments?

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

Principal Display Panel

COMPARE TO DULCIOLAX® STOOL SOFTENER ACTIVE INGREDIENT**

Stool Softener

DOCUSATE SODIUM 100 mg • STOOL SOFTENER LAXATIVE

Fast, dependable relief of occasional constipation

SOFTGELS

**This product is not manufactured or distributed by Chattem, Inc., distributor of Dulcolax® Stool Softener

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 ASSOCIATED LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

www.topcarebrand.com

Product Labeling

PLD-6671B
FC006744
Exp. Date:
Lot No.:

QUALITY GUARANTEED

0 36800 16032 3

NDC 36800-00808-25

TopCare
health

**COMPARE TO DULCOLAX®
STOOL SOFTENER
ACTIVE INGREDIENT****

Stool Softener

DOCUSATE SODIUM 100 mg • STOOL SOFTENER LAXATIVE

**Fast, Dependable Relief
of Occasional Constipation**

25 SOFTGELS actual size



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ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



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call 1-888-423-0139

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*This product is not manufactured or distributed by Chatham, Inc., distributor of Dulcolax® Stool Softener.

Drug Facts (continued)	Questions or comments? Call toll free 1-888-423-0139
Other information	
<ul style="list-style-type: none"> ■ each softgel contains: sodium 5 mg ■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F) 	
Inactive ingredients	
polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol	
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TOPCARE Stool Softener

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-862
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
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)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-862-25	1 in 1 BOX	02/28/2020	
1		25 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	02/28/2020	

