

**STOOL SOFTENER- docusate sodium capsule, liquid filled
TOP CARE (Topco Associates LLC)**

Drug Facts

Active ingredient (in each softgel)

Docusate sodium 100 mg

Purpose

Stool softener laxative

Uses

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

Warnings

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

presently taking mineral oil.

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 | take 1 to 3 softgels daily. This

children 12 years and over	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 6 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

*contain one or more of these ingredients

Questions or comments?

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

Principal Display Panel

COMPARE TO DULCOEASE® 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 Boehringer Ingelheim Pharmaceuticals, Inc., distributor of DulcoEase®.

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

©TOPCO PLVA0618

topcare@topco.com

www.topcarebrand.com

Product Labeling

Exp. Date: _____

Lot No.: _____

FC004460

PLD-E10J

Visit here for more information:
<http://topbrands.com/48z7rs>

0 36800 16032 3



NDC 36800-584-25

TopCare
health™

COMPARE TO DULCOEASE®
STOOL SOFTENER
ACTIVE INGREDIENT**

Stool Softener

DOCUSATE SODIUM 100mg • STOOL SOFTENER LAXATIVE

Fast, Dependable Relief
of Occasional Constipation

25 SOFTGELS actual size



DISTRIBUTED BY TOPCO ASSOCIATES LLC
 ELK GROVE VILLAGE, IL 60007
 ©TOPCO PLVA0618
 QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

GLUTEN FREE

QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Drug Facts (continued)

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 edible ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, contains one or more of these ingredients

Questions or comments? Call toll free 1-888-423-0139

**This product is not manufactured or distributed by Boehringer Ingelheim Pharmaceuticals, Inc., distributor of Dulcolase®.

Drug Facts

Active ingredient (in each softgel) Docusate sodium 100 mg.....Stool softener laxative

Uses

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

Warnings

- Ask a doctor before use if you have
 - stomach pain
 - nausea
 - vomiting
- a sudden change in bowel habits lasts more than 2 weeks
- Ask a doctor or pharmacist before use if you are presently taking mineral oil.
- 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
 - 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

TOPCARE Stool Softener

STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-584
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 (clear)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P51;SCU1;D2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-584-25	1 in 1 BOX	07/31/2018	12/31/2024
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 Drug	M007	07/31/2018	12/31/2024

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

