

**STOOL SOFTENER LAXATIVE- 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

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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 toll free 1-888-423-0139

Principal Display Panel

COMPARE TO THE COLACE® REGULAR STRENGTH STOOL SOFTENER ACTIVE INGREDIENT†

Stool Softener

DOCUSATE SODIUM, 100 mg LAXATIVE

- Gentle
- Dependable
- stimulant-Free

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.

DISTRIBUTED BY


TOPCO ASSOCIATED LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

www.topcarebrand.com

Product Labeling




NDC 36800-778-10

COMPARE TO COLACE® REGULAR STRENGTH STOOL SOFTENER ACTIVE INGREDIENT!

Stool Softener

DOCUSATE SODIUM, 100 mg • LAXATIVE

- Gentle • Dependable
- Stimulant-Free



100 SOFTGELS actual size

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 Docusate sodium 100 mg.....Stool softener laxative

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Drug Facts (continued under label)

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 TOPCO ASSOCIATES LLC
 ELK GROVE VILLAGE, IL 60007
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 QUESTIONS? 1-888-423-0139
 topcare@topco.com
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✓ QUALITY GUARANTEED



PLD-C2L 0 36800 08462 9

Lot No.:
 LB005024

Exp. Date:

PEEL HERE ↓

Drug Facts (continued)

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TOPCARE HEALTH Stool Softener

STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-778
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: 3WJQ05DW1A)	
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:36800-778-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2018	12/31/2024
2	NDC:36800-778-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2018	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	03/31/2018	12/31/2024

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

Revised: 11/2023

TOP CARE (Topco Associates LLC)