

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

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**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
- 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 (1-800-222-1222) 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 5 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

### Inactive ingredients

ammonium hydroxide, anhydrous citric acid, D&C red #33, ethyl alcohol, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, n-butyl alcohol, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

### Questions or comments?

Call **1-888-309-9030**

### Principal Display Panel

#### **COMPARE TO COLACE® REGULAR STRENGTH STOOL SOFTENER ACTIVE INGREDIENT**

Stool Softener

DOCUSATE SODIUM 100 mg

STOOL SOFTENER LAXATIVE

- Gentle
- Dependable
- Stimulant-free

SOFTGELS

\*\*This product is not manufactured or distributed by Avrio Health L.P., distributor of Colace® Regular Strength 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 ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

[www.topcarebrand.com](http://www.topcarebrand.com)

**Product Label**

NDC 36800-638-60




COMPARE TO COLACE® REGULAR STRENGTH STOOL SOFTENER ACTIVE INGREDIENT†

# Stool Softener

DOCUSATE SODIUM 100 mg  
STOOL SOFTENER LAXATIVE

- Gentle
- Dependable
- Stimulant-Free



actual size

## 60 SOFTGELS

**Drug Facts**

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Docusate sodium 100 mg.....	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 (1-800-222-1222) right away.

**Directions**  
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**Drug Facts (continued)**

**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** ammonium hydroxide, anhydrous citric acid, D&C Red #33, ethyl alcohol, FD&C blue #1, FD&C red #40, FD&C yellow # 6, gelatin, glycerin, isopropyl alcohol, lecithin, mineral oil, n-butyl alcohol, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide


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

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



Scan here for more information or call 1-888-423-0139



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



PLD-D705A  
FC007502

Lot No.:  
Exp. Date:

**TOPCARE HEALTH Stool Softener Laxative**

<b>STOOL SOFTENER LAXATIVE</b>			
docusate sodium capsule, liquid filled			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-638
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	

**Product Characteristics**

<b>Color</b>	red, white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	PC18
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-638-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2021	
2	NDC:36800-638-60	1 in 1 BOX	02/05/2021	
2		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:36800-638-10	1 in 1 BOX	02/05/2021	
3		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 Drug	M007	02/05/2021	

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

Revised: 6/2024

TOP CARE (Topco Associates LLC)