

**TOPCARE STOOL SOFTENER- docusate sodium capsule, liquid filled**  
**TopCo Associates, LLC**

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**420 Topcare Stool Softener**

**Active ingredient(s)**

Docusate sodium 100mg

**Purpose**

Stool softener

**Use(s)**

- 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 a period of 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 stool softener laxative for more than 1 week

**Pregnancy/Breastfeeding**

ask a health professional before use.

**Keep out of reach of children**

In case of accidental 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 capsule contains: sodium 5mg
- VERY LOW SODIUM

### Storage

- store 25°C (77°F) excursions permitted between 15°- 30°C (59°-86°F)

### Inactive ingredients

Black edible ink, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special

### Questions

Call 1-888-952-0050 Monday through Friday 9am-5pm

### Principal Display Panel

**TopCare** health

**Stool Softener**  
DOCUSATE SODIUM, 100 mg  
LAXATIVE

- Gentle
- Dependable
- Stimulant-Free

**60 SOFTGELS**

NDC 76162-006-60

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

<b>Drug Facts</b>	<b>Purpose</b> Stool softener
<b>Active ingredient (in each softgel)</b> Docusate sodium 100mg	<b>Uses</b> ■ relieve occasional constipation (irregularity) ■ generally produces bowel movement in 12 to 72 hours
<b>Warnings</b> 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 a period of 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 stool softener for more than 1 week. If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
<b>Directions</b> ■ 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 of age: ■ ask a doctor	
<b>Other information</b> ■ each capsule contains sodium 5mg ■ VERY LOW SODIUM ■ store at 25°C (77°F) excursions permitted between 15°- 30°C (59°-86°F)	
<b>Inactive ingredients:</b> black edible ink, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special	
<b>Questions or Comments?</b> Call 1-888-424-0138	

Stool Softener

4.625"



**Stool Softener**

**TOPCARE STOOL SOFTENER**

docusate sodium capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76162-006
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)		DOCUSATE SODIUM	100 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
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 400 (UNII: B697894SGQ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
WATER (UNII: 059QF0KO0R)				
<b>Product Characteristics</b>				
Color	red, white	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	PC18	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-006-60	1 in 1 CARTON	04/10/2015	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:76162-006-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2015	
3	NDC:76162-006-81	400 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2015	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M007	04/10/2015		

**Labeler** - TopCo Associates, LLC (006935977)