# 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)

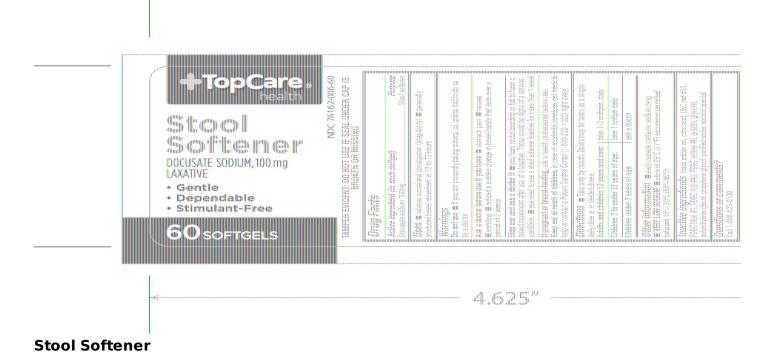
# **Inactive ingredients**

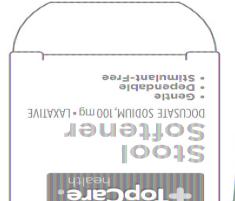
Black edible ink, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special

### Questions

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

# **Principal Display Panel**





### Orugi Facits

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

LB1811 R0421

### Drug Facts (continued)

### Directions

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# Questions or comments? Call 1-888-423-0139

\*This product is not manufactured or distributed by Purdue Pharma L.P., owner of the registered

trademark Colace®.



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

# loo(date



# Stool Softener

DOCUSATE SODIUM, 100 mg LAXATIVE

- Gentle
- Dependable
- Stimulant-Free

# 60softgels



LOT NO.

EXP.



### Stool Softener

# TOPCARE STOOL SOFTENER

docusate sodium capsule, liquid filled

### **Product Information**

HUMAN OTC DRUG **Item Code (Source)** NDC:76162-006 **Product Type** 

**Route of Administration** ORAL

# **Active Ingredient/Active Moiety**

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

Inactive Ingredients		
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)		

Product Characteristics				
Color	red, white	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	PC18	
Contains				

P	Packaging			
#	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	

Marketing Information			
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)

Revised: 2/2021 TopCo Associates, LLC