

**STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled  
Cardinal Health (Leader) 70000**

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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 **1-877-753-3935** Monday-Friday 9AM-5PM EST

### Principal Display Panel

COMPARE TO COLACE® REGULAR STRENGTH 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 HealthL.P., distributor of Colace® Regular Strength.

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

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

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

# Product Label

**LEADER**<sup>TM</sup>

NDC 70000-0091-3

# Stool Softener

Docusate Sodium, 100 mg  
Stool Softener Laxative

Gentle  
Dependable  
Stimulant-Free

Actual Size

**750 SOFTGELS\*\***  
\*\*Liquid-Filled Capsules

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

<b>Drug Facts</b>	<p><b>Active ingredient (in each softgel)</b> Docusate sodium 100 mg.....Stool softener laxative</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ relieves occasional constipation (irregularity)</li> <li>■ generally produces bowel movement in 12 to 72 hours</li> </ul> <p><b>Warnings</b></p> <p>Do not use if you are presently taking mineral oil, unless told to do so by a doctor.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ stomach pain</li> <li>■ nausea</li> <li>■ vomiting</li> </ul> <p>■ noticed a sudden change in bowel habits that lasts over 2 weeks</p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.</li> <li>■ you need to use a laxative for more than 1 week</li> </ul> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ take only by mouth. Doses may be taken as a single daily dose or in divided doses.</li> <li>adults and children 12 years and over take 1-3 softgels daily</li> <li>children 2 to under 12 years of age take 1 softgel daily</li> <li>children under 2 years ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ each softgel contains: sodium 5 mg</li> <li>■ store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)</li> </ul> <p><b>Inactive ingredients</b> ammonium hydroxide, anhydrous citric acid, D&amp;C Red #33, ethyl alcohol, FD&amp;C blue #1, FD&amp;C red #40, FD&amp;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</p> <p><b>Questions or comments?</b> Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>
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CIN 5599269 REV. 2/21

0 96295 13852 8

Exp. Date: \_\_\_\_\_

## LEADER Stool Softener Laxative

STOOL SOFTENER LAXATIVE			
docusate sodium capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0091
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: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6O92ICV9RU)			

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	

### 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:70000-0091-3	750 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2021	
2	NDC:70000-0091-2	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2021	
3	NDC:70000-0091-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/31/2021	

**Labeler** - Cardinal Health (Leader) 70000 (063997360)

Revised: 1/2024

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